absence of a DV for *trans* fat, to inform consumers of recommendations concerning its consumption.

While the online survey was small, its results support concerns expressed by the food industry that some consumers would interpret the footnote as a de facto DV of zero or as a warning statement that they should avoid all *trans* fat. The agency agrees with comments that this interpretation is inconsistent with dietary guidance given in the IOM/NAS report to keep intake of *trans* fat "as low as possible while consuming a nutritionally adequate diet" (Ref. 140), as well as guidance in the Dietary Guidelines 2000 to cut back on saturated and *trans* fats when reducing total fat intake (Ref. 87) or in the 2001 NCEP report to keep the intake of *trans* fatty acids low (Ref. 89). FDA also agrees that these scientific reviews have similar dietary recommendations for the intake of saturated fat and cholesterol that are important for consumers to take into consideration when making decisions about heart-healthy dietary choices. The agency addressed only *trans* fat in the footnote statement, not because saturated fat or cholesterol had different recommendations or were less important, but because they have established DVs from which to determine the % DV for nutrition labeling purposes.

The agency agrees with comments that support consumer testing to ensure that information on the food label provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. FDA concludes, therefore, that based on arguments presented in the comments, it is premature to require the use of the proposed footnote statement in the nutrition label without further research. Consumer research would likely need to provide information on the impact of the statement in a footnote on consumers' food selections.

Accordingly, as a result of concerns expressed in the comments, asserting that consumers may place undue emphasis on *trans* fat information relative to other heart-unhealthy fats from the presence of the *trans* fat proposed footnote, the agency is not proceeding at this time to incorporate a requirement for a footnote statement in this final rule. Instead, FDA is issuing an advance notice of proposed rulemaking (ANPRM) elsewhere in this issue of the **Federal Register** that will solicit comment and additional consumer research on the use of a footnote and the language that may be used in a footnote to better reflect the dietary recommendations given in the previously-mentioned scientific reviews. In light of the need for consumer research on possible footnote statements to evaluate consumers' understanding of the totality of dietary recommendations that address the selection of foods for a heart-healthy diet, the agency notes in the ANPRM that it intends to conduct such research and looks forward to receiving additional research from other interested parties.

In the meantime, as noted in the preceding comment, FDA is issuing this final rule to require the quantitative declaration of *trans* fat in the Nutrition Facts panel. As noted earlier, most comments that opposed the proposed footnote stated a belief that even in the absence of a DV, consumers can still find quantitative information useful, and pointed to current labeling of mono- and polyunsaturated fats. In light of previous research that shows that consumers often use information on the Nutrition Facts panel to compare levels of nutrients in two or more foods, FDA concludes that it is important to proceed to list the quantitative information on *trans* fat at this time so that consumers will have information to use in comparing products and making dietary selections to reduce their intake of *trans* fat. The agency believes a

footnote about saturated fat, cholesterol, and *trans* fat may provide additional assistance to convey the relative importance of each of these fats to consumers in a manner which enables them to understand their relative significance, to each other and in the context of a total daily diet. However, because of the public health impact of CHD in the United States and the additional time it will take to conduct the necessary consumer research, the agency concludes that it is essential to proceed at this time to mandate the listing of the quantitative information on *trans* fat so that consumers will be able to use that information to help maintain healthy dietary practices and to address an added footnote statement at a later time.

FDA acknowledges concerns, expressed in response to the November 2002 notice (67 FR 69171) to reopen the comment period, about the shortness of the comment period and requests to extend the comment period. However due to the high level of interest in the public health and economic aspects of this rule, the agency did not believe it was in the public interest to provide for additional time for comment. A longer comment period, however, will be provided for the ANPRM being published elsewhere in this issue of the **Federal Register**.

(Comment 18) A few comments requested that the term "*trans* fatty acids" not be used interchangeably with "*trans* fat" as proposed in § 101.9(c)(2)(i)(B) in the November 1999 proposal. These comments stated that the term "fatty acid" would be confusing to consumers and is inconsistent with the terminology used in nutrition labeling and claims for other fatty acids, i.e., "saturated fat," "polyunsaturated fat," and "monounsaturated fat." The comments stated that while "fatty acid" is technically correct, labels should use the easier term to understand, i.e., "*trans* fat."

The agency agrees that there should be consistent terminology used on the food label and notes that proposed § 101.9(c)(2)(i)(B), which dealt primarily with the proposed footnote about *trans* fat content, is deleted from this final rule. The agency did not move the sentence providing for the use of the term "*trans* fatty acids" to new § 101.9(c)(2)(ii). Therefore, the term "fatty acids" is not to be used on the Nutrition Facts panel.

Conforming Amendments

Because this final rule is making *trans* fat a mandatory nutrient to be placed on a separate line in nutrition labeling, there are a number of conforming amendments throughout § 101.9 that must be made. Section 101.9(c) requires that information on mandatory nutrients, such as saturated fat and *trans* fat, be included in all nutrition labeling unless otherwise excepted from such labeling as provided for in specified paragraphs.

Special provisions within § 101.9(c) allow for shortened formats that provide manufacturers flexibility to omit noncore nutrients (i.e., mandatory nutrients other than calories, total fat, sodium, total carbohydrate, and protein) that are present in insignificant amounts from the list of nutrients and group them in a summary statement at the bottom of the label that states "Not a significant source of _____" (see 58 FR 2079 at 2083, Comment 8, January 6, 1993). These special provisions are found in § 101.9(c)(1)(ii) for calories from fat, § 101.9(c)(2)(i) for saturated fat, § 101.9(c)(3) for cholesterol, § 101.9(c)(6)(i) for dietary fiber, § 101.9(c)(6)(ii) for sugars, and § 101.9(c)(8)(iii) for vitamin A, vitamin C, calcium, or iron. For consistency with the labeling scheme for these other noncore mandatory nutrients, new § 101.9(c)(2)(ii) provides that if the *trans* fat content is not required and, as a result, not declared, the statement "Not a significant source of *trans* fat" must be placed at the bottom of the

table of nutrient values. Also, for added consistency, new § 101.9(c)(2)(ii) will point to an exception to this requirement under § 101.9(f). Section 101.9(f) provides for a simplified format to be used on labels of products containing insignificant amounts of more than half the nutrients required to be in the Nutrition Facts label. Except as specified in § 101.9(f)(4), products that qualify for the simplified format do not have to use the statement "Not a significant source of _____" for noncore nutrients that are omitted from the label under § 101.9(c). An example of such an exception would include when nutrition claims are made for the product.

Current § 101.9(c)(2)(i) requires label declaration of saturated fat content information on a separate line (the "Not a significant source of ____" statement would not be an option), if claims are made about fat or cholesterol and if "calories from saturated fat" is declared. In the November 1999 proposal, § 101.9(c)(2)(i) was amended to also require label declaration of saturated fat content information when claims are made about fatty acids. Current § 101.9(c)(2)(i) did not include claims about fatty acids because at the time that regulation was proposed (56 FR 60478, November 27, 1991), it was thought unnecessary since no claims were proposed for fatty acids that were present at less than 0.5 g per reference amount. However, when the "saturated fat free" claim was established in the final rules (58 FR 2302 at 2331), FDA inadvertently did not amend § 101.9(c)(2)(i) to require the declaration of saturated fat content on a separate line when fatty acid claims were made. As a result, the declaration of saturated fat content was not required when "saturated fat free" claims were made. This is inconsistent with regulations governing claims for all other nutrients that require the listing of the nutrient that is the subject of the claim within the Nutrition Facts panel so that

consumers can easily find quantitative information supporting claims made for a product. Because no comments objected to the proposed requirement in the November 1999 proposal for a label declaration of saturated fat content when fatty acid claims are made, which would require that saturated fat content be listed when a "saturated fat free" claim is used, FDA is finalizing this part of the regulation as proposed. Similarly, new § 101.9(c)(2)(ii) also requires label declaration of *trans* fat content information if claims are made about fat, fatty acids, or cholesterol.

In reference to the statement "Not a significant source of _____" that is to be placed at the bottom of the list of nutrient values, the agency proposed in the November 1999 proposal (64 FR 62746 at 62757) to remove the phrase "in the same type size" in § 101.9(c)(2)(i) where it refers to the size of the statement. This action was intended to correct a technical error in the regulations caused by the fact that current § 101.9(d)(1)(iii) allows the statement, along with all footnotes, to be in type size no smaller than 6 point type while it requires the listing of nutrient values to be in type size no smaller than 8 point type. Accordingly, the phrase "in the same type size" in § 101.9(c)(2)(i) would require the "Not a significant source of ____" statement to be in 8 point type, conflicting with § 101.9(d)(1)(iii). This technical error was addressed in amendments published on August 18, 1993 (58 FR 44063 at 44065–66). To correct the problem, FDA stated at that time (58 FR 44063 at 44065–66) that it was removing the sentence from § 101.9(c)(8)(iii) that required the "Not a significant source of ___" statement to be in the same type size as nutrients listed in the Nutrition Facts panel. However, the agency failed to notice the same error in § 101.9(c)(2)(i), (c)(3), (c)(6)(i), and (c)(6)(ii). Inadvertently, the conflicting sentence was never removed from

§ 101.9(c)(8)(iii), nor were the statements requiring "in the same type size" removed from any of the other paragraphs. In this final rule, FDA is making the correction in § 101.9(c)(2)(i) and in new § 101.9(c)(2)(ii). The agency intends to remove the phrase "in the same type size" from the remaining sections of § 101.9(c) in the future.

In addition, current nutrition labeling rules provide exemptions for select nutrients when food products qualify for simplified formats (see § 101.9(f)).

FDA is revising § 101.9(f) that pertains to the use of a simplified format when a food product contains insignificant amounts of seven or more of the mandatory nutrients. This section implements section 403(q)(5)(C) of the act, which states that "If a food contains insignificant amounts ... of more than one-half the nutrients required * * * to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary." Current regulations considered 13 required nutrients (calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron) and calculated "more than one-half" to mean that seven or more nutrients must be at insignificant levels for a product to use the simplified format (58 FR 2709 at 2140, comment 173). Accordingly, in conformance with the statutory requirements, the inclusion of *trans* fat as a mandatory nutrient results in a total of 14 required nutrients. This new total necessitates changing the number of nutrients that must be present in insignificant amounts in § 101.9(f) from seven to eight to qualify a food for the simplified format. Therefore, FDA is revising § 101.9(f) to state "The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following:

Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron * * *''

FDA is modifying sample labels throughout § 101.9 to be consistent with the revisions described previously. The citations for the sample labels that have been modified are as follows: § 101.9(d)(11)(iii) (the tabular display of the nutrition label), paragraph (d)(12) (the full nutrition label), paragraph (d)(13)(ii) (an example of an aggregate nutrition label), and paragraph (e)(5) (nutrition information presented for a food "as purchased" and "as prepared"). Likewise, the sample labels in § 101.9(j)(13)(ii)(A)(*1*) and (j)(13)(ii)(A)(*2*) (tabular display and linear displays, respectively, of nutrition labels for foods in packages with a total surface area available to bear labeling of 40 or less square inches) are also being revised to include *trans* fat.

Other conforming amendments to § 101.9 that are required as a result of this rulemaking include revisions to paragraphs (g)(5) and (g)(6) that inform the industry of how FDA will determine compliance with this section. Paragraph (g)(5) addresses those nutrients for which dietary guidance generally recommends limitations on intake. Accordingly, FDA will include *trans* fat as one of the nutrients that are deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite sample is greater than 20 percent in excess of the value for that nutrient declared on the label. Likewise, § 101.9(g)(6) is being revised to state that reasonable deficiencies in a food of calories and specified nutrients, including *trans* fat, under labeled amounts are acceptable within current good manufacturing practice.

Section 403(q)(5)(F) of the act specifies that dietary supplement products shall bear nutrition labeling "in a manner which is appropriate for the product

and which is specified in regulations... ." Accordingly, FDA issued regulations in § 101.36 that specify the nutrition information that must be on the label or labeling of dietary supplements (62 FR 49826, September 23, 1997). In the November 1999 proposal, FDA proposed to amend § 101.36 to maintain consistency in the nutrition labeling of conventional foods and of dietary supplements. Comments unanimously supported revising § 101.36 to be consistent with § 101.9 as it pertains to the provisions for *trans* fat. Accordingly, FDA is revising paragraph § 101.36(b)(2)(i) to provide for *trans* fats in the nutrition labeling of dietary supplements.

This final rule also impacts on the voluntary nutrition labeling program of raw fruits, vegetables, and fish in that § 101.45(a)(2) requires that nutrients be declared in accordance with § 101.9. However, because section 403(q)(4)(A) of the act requires the Secretary, and by delegation FDA, to furnish nutrition information for that program and the agency has proposed to update those values (67 FR 12918, March 20, 2002), the agency is deferring action on § 101.45 until a final rule is published on that rulemaking.

C. Definition of Trans Fatty Acids

In the November 1999 proposal, FDA defined *trans* fatty acids as "unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration (64 FR 62746 at 62757).

(Comment 19) Most of the comments on the definition of *trans* fat supported the proposed definition that excludes fatty acids with conjugated bonds, stating that *trans* fatty acids with conjugated bonds are metabolized differently than those with nonconjugated bonds and that this definition adequately identifies the fatty acids intended to be covered by the rule. A few comments recommended that *trans* fatty acid precursors of conjugated linoleic

acid (CLA) should also be excluded from the definition. These comments noted that *trans*-vaccenic acid (*trans*–11 18:1), which is the dominant *trans* fatty acid in products of ruminant origin (e.g., cows' milk), can be desaturated in the body and converted to CLA. For this reason, the comments recommended that *trans* fatty acids of ruminant origin not be included in the definition of *trans* fatty acids.

Other comments stated that *trans* fatty acids with conjugated bonds should be included in the definition of "*trans* fatty acids."

Another comment requested that FDA explicitly state that the rules on the labeling and claims for *trans* fatty acids apply equally to naturally occurring *trans* fats.

FDA notes that the comments requesting that *trans* vaccenic acid and other *trans* fatty acids of ruminant origin be excluded from the definition of *trans* fatty acids and that fatty acids with conjugated bonds be included focused on functional or metabolic aspects of these compounds (e.g., their metabolic *trans*formations to other types of fatty acids) rather than on their actual chemical structures. Since most of the comments agreed with the proposed definition, which identifies *trans* fatty acids by their chemical structures, the agency is taking no action in response to suggestions to define *trans* fatty acids by their functional attributes. Thus for the purposes of this rule, the origin of the *trans* fatty acid does not matter. *Trans* vaccenic acid, a *trans* fatty acid with a single double bond, and other *trans* fatty acids of ruminant origin with either a single double bond or nonconjugated double bonds are included in this chemical definition of *trans* fatty acids. *Trans* fatty acids with conjugated bonds will not be included because they do not meet the Agency's regulatory chemical definition of *trans* fatty acids which is "all unsaturated fatty acids

that contain one or more isolated double bonds in a *trans* configuration." FDA notes also that while the proposal combined saturated fat and *trans* fatty acids on a single line, this final rule provides for a separate line for *trans* fat. The declarations of saturated fat and *trans* fat will now be separate and both declarations will be based on chemical definitions of these components. Again, *trans* fatty acids, regardless of origin, that meet the above definition are to be included in the label declaration of *trans* fat.

FDA notes that, in classifying fatty acids, the IOM report on macronutrients uses a chemical definition of *trans* fatty acids that differs from FDA's regulatory chemical definition. The IOM report includes all fatty acids with a double bond in the *trans* configuration in the broad category of *trans* fatty acids (Ref. 140). Thus, the IOM definition includes both conjugated and non-conjugated double bonds in the *trans* configuration, whereas FDA's definition only includes *trans* fatty acids with nonconjugated double bonds. In addition, the IOM report considers conjugated linoleic acid as a collective term for geometric and positional fatty acids in which the double bonds (*trans* and/or *cis*) are conjugated. In the IOM report, the categories, *trans* fatty acids and conjugated linoleic acid, overlap. Under FDA's definition, conjugated linoleic acid would be excluded from the definition of *trans* fat. Thus, using FDA's regulatory chemical definition, the categories "*trans* fatty acids" and "conjugated fatty acids" are mutually exclusive. The definition of *trans* fatty acids, excluding fatty acids with conjugated double bonds, is consistent with the way that *cis* isomers of polyunsaturated fatty acids are defined in redesignated § 101.9(c)(2)(iii).

D. Methodology

(Comment 20) One comment asked whether the Association of Official Analytical Chemists (AOAC) Official Method 996.01 can be used for measuring *trans* fat in foods. The comment noted that, at present, AOAC Official Method 996.01 is the ideal method for the measurement of total fat, saturated fat, and mono- and polyunsaturated fat in foods. The comment noted further that AOAC Official Method 996.01 was originally intended for cereal products containing 0.5–13 percent total fat and that recently, a study by Ali et al. (Ref. 30) demonstrated its applicability to all types of food matrices with fat contents ranging from 0.7 to 97.5 g/100 g food. The comment noted that the method of Ali et al. (Ref. 30) used an SP–2560 fused silica capillary column (100 meters (m) x 0.25 millimeter (mm)) and can be used for the accurate determination of *trans* fatty acids. The comment noted that if appropriate gas chromatography (GC) operating conditions are selected, the SP–2560 column as well as columns of similar polarity give a very good separation of *cis* and *trans* isomers.

FDA notes that, as currently written, AOAC Official Method 996.01 is not suitable for quantifying *trans* fatty acids for food labeling purposes because the capillary column specified (i.e., 30 m x 0.25 mm id., 0.2 μm film, non-bonded 90 percent cyanopropyl, 10 percent phenyl siloxane) is not sufficiently long to obtain adequate separation of the *cis* and *trans* fatty acids. Ali et al., (Ref. 30) modified the method and used a 100 m flexible fused silica column (SP–2560, 100 m x 0.25 mm id., 0.20 μm film thickness) to obtain better separation of isomers in food samples. Specifically, better resolution in the complex 18:1 and 18:2 regions was obtained with the longer column. FDA has found that when appropriate operating conditions are selected, the SP–2560 column and other columns of similar polarity give a very good separation of

cis and *trans* isomers. We point out, however, that the modification described by Ali et al., (Ref. 30) has not been subjected to a collaborative study and is not an official method.

It is important to note that FDA regulations do not specify the methodology that firms are to use in obtaining values for nutrition labeling purposes. Rather, under § 101.9(g)(2), FDA determines compliance with nutrition labeling rules by using appropriate analytical methods "as given in the 'Official Methods of Analysis of the AOAC International' 15th Ed. (1990) or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures." Firms may choose to use a method other than that which the agency uses to determine compliance, but the firm would be subject to, for compliance purposes, a method the agency considers appropriate under § 101.9(g). With respect to analysis of fats (including *trans* fat), FDA laboratories utilize the most recent editions (including revisions of methods from the Association of Official Analytical Chemists International (AOACI; *Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002; AOAC International, Gaithersburg, MD) (Ref. 143) and the American Oil Chemists Society (AOCS; *Official Methods and Recommended Practices of the AOCS*, 2002–2003 Methods-Additions and Revisions, AOCS Press, Champaign, IL) (Ref. 144)).

(Comment 21) Several comments asked that FDA recognize AOAC Method 996.06 as modified in the *Journal of the Association of Official Analytical Chemists* in January 2000, as a suitable method for the analysis of *trans* fatty acids for food labeling purposes.

FDA points out that recommendations for the modification of AOAC Official Method 996.06 (Ref. 105) were published in the *Journal of the*

Association of Official Analytical Chemists (Ref. 106). The recommendations are based on the work of DeVries et al. 1999 (Ref. 107). DeVries and coworkers report that while quantitation of fat in foods has been performed successfully with AOAC Official Method 996.06, a number of situations have been encountered that render the following method note inaccurate: "For any unknown or uncalibrated peaks, use the nearest calibrated fatty acid response factors and conversion factors" (Ref. 107). Specifically, the identification of extraneous compounds and availability of additional standard fatty acid methyl esters combined with mass spectral data led to the recommendation of modifications in AOAC Official Method 996.06.

Specific recommendations for modifications include recommendations that the column requirements for the method be changed to a performance-based specification such that a capillary column capable of separating adjacent peaks of C18:3 and 20:1 and the fatty acid methyl ester trio of adjacent peaks of C22:1, C20:3 and C20:4 with a resolution of 1 or greater be used. Column SP–2560, 100 m x 0.25 mm with a 0.20 μm film was identified as a suitable column.

The recommendations referenced in the paragraph above have now been incorporated into AOAC Method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002; chapter 41.1.28A) (Ref. 105). This method is suitable for use in a wide range of food matrices for measuring *trans* fat for labeling purposes.

AOAC Method 996.06 cited above for *trans* fat analysis is the most current AOAC gas chromatography method available and FDA will consider it an appropriate method under § 101.9(g)(2) for determining compliance with nutrition labeling provisions for *trans* fat. AOAC Method 996.06 is not

included in the 15th edition (1990) of *Official Methods of Analysis of AOAC International* (which is incorporated by reference in § 101.9(g)(2)) because the process of development and validation of this method was not completed until 1996. Therefore, AOAC Method 996.06 as it is reported in Revision 1, 2002 of the 17th edition of *Official Methods of Analysis of AOAC International* (Ref. 105) may be used as an "other reliable and appropriate analytical procedure" as provided for in § 101.9(g)(2). FDA intends to propose amendments in the future on the edition of the AOAC method listed in § 101.9(g)(2) and other needed revisions of § 101.9.

(Comment 22) One comment noted that detection methodology is not sophisticated enough to accurately measure *trans* fat in all food products. The comment stated that significant work is needed to validate the AOCS methods for food matrices other than fat and oils.

FDA disagrees with this statement. While the agency recognizes that AOCS methods have not been extended to cover matrices other than fats and oils, the AOAC method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002) (Ref. 105) is suitable for the analysis of *trans* fat in a wide range of foods of varying fat content. As noted in comment 19, above, AOAC Method 996.01 is not suitable for quantifying *trans* fatty acids for food labeling purposes because the capillary column specified is not sufficiently long to obtain adequate separation of the *cis* and *trans* fatty acids.

(Comment 23) A few comments recommended that FDA consider listing amounts of *trans* fat to the nearest tenth or hundredth of a gram, rather than to the nearest 0.5 g. One of these comments stated that Canada has established a rounding limit of 0.1 g for food labeling indicating that analytical methods are capable of detecting that amount.

FDA disagrees with these recommendations. FDA notes that while these recommended levels might be quantifiable by laboratories using GC methodology such as that described in AOAC method 996.06 (*Official Methods of Analysis of AOAC International,* 17th edition, Revision 1, 2002) (Ref. 105), they will pose a problem for laboratories that are set up to quantitate *trans* fatty acids by infrared spectroscopy (IR) methodology because the detection limits of the currently available IR methods are higher than those of the GC methods. More importantly, however, there are no unambiguous methods for confirming the very low levels suggested by the comment.

Moreover, FDA notes that the increment for listing *trans* fat is consistent with increments used for listing total fat and saturated fat. Therefore, the agency is finalizing § 101.9(c)(2)(ii) to state that *trans* fat shall be expressed, as proposed, to the nearest 0.5 g increment below 5 g and to the nearest gram increment above 5 g.

(Comment 24) One comment noted that the IR method of choice in the November 1999 proposal, AOCS Recommended Practice Cd 14d–96 (Ref. 45), generally overestimates *trans* fat at low levels because of interferences and issues with both accuracy and detection limits. The comment noted further that the AOCS GC method Ce 1f–96 (Ref. 46) has better sensitivity, but has not been validated for many types of food products and that significant work is needed to validate this method for other food matrices.

FDA agrees that the detection limits of the AOCS GC method (Ce 1f-96) (Revised 2002, Ref. 146) are lower than those of the AOCS IR recommended practice (Cd 14d-96) (Revised 1999, Ref. 145). FDA notes that AOCS Recommended Practice Cd-14d-96 is applicable to the determination of isolated *trans* double bonds in natural or processed oils and fats with *trans*

levels equal or greater than about 0.8 percent. The lower limit of quantitation for this IR recommended practice may be higher (i.e., the method may be less accurate for determination of low levels of *trans* fat) for complex systems such as commercial food products (Ref. 145).

The AOCS Official Method Ce 1f–96 (Ref. 146) is designed to evaluate the level of *trans* isomers formed during refining or during hydrogenation of vegetable oils or fats and the scope of the method does not extend beyond these matrices. FDA notes that the recent improvements in AOAC Official Method 996.06 as referenced in Revision 1, 2002 (Ref. 105), have resulted in the applicability of this GC method to a wide range of food products.

(Comment 25) One comment asked if *trans* fat values below 0.5 g are to be declared as "0," how FDA will address the labeling of foods like butter, where *trans* fat content fluctuates seasonally above and below 0.5 g per serving. The comment stated that FDA should err on the side of conservatism and require that labeling be based on the highest levels found in such products over the entire year.

FDA has long recognized that variations occur naturally in the nutrient content of foods. The compliance procedures that FDA follows, which are found in § 101.9(g)(2), provide that a sample for nutrient analysis must consist of a composite of 12 subsamples, taken one from each of 12 randomly chosen shipping cases. FDA will then analyze the nutrient content of this composite test sample. Upon determination of the laboratory analyses, FDA uses the compliance procedures set forth in § 101.9(g)(5) and (g)(6) to determine if the values declared for those nutrients that have recommended dietary limits, such as saturated fat and cholesterol, misbrand the label. The content of a sample composite of these nutrients is in compliance if the analyzed value is no more

than 20 percent greater than the value declared on the label. Stated another way, for nutrients listed in § 101.9(g)(5), the ratio between the nutrient level obtained by laboratory analysis and the product's label value, multiplied by 100, cannot be greater than 120 percent for the product to be in compliance. For example, if the laboratory value is 4 grams, and a product's label value is 2 gram, the ratio (4/2) x 100 = 200 percent. This value is greater than 120 percent, hence, the product is out of compliance.

FDA did not address this issue in the proposal because the declaration of "saturated fat" included *trans* fats, and saturated fats are addressed in § 101.9(g)(5) and (g)(6). Now that FDA is requiring that *trans* fat be declared in the main body of the nutrition label (i.e., the amount of *trans* fat is not in a footnote), FDA is making a conforming amendment to § 101.9(g)(5) and (g)(6) to include *trans* fatty acids.

FDA's policy since the 1970s assigns the manufacturer the responsibility for assuring the validity of a product label's stated nutrient values (Ref. 108). Accordingly, the source of the data used to calculate nutrition labeling values is the manufacturer's prerogative, but FDA's policy recommends that the nutrient values for labeling be based on product composition, as determined by laboratory analysis of each nutrient. If a manufacturer knows that a nutrient is likely to vary over seasons or due to other factors (e.g., location, growing conditions, product *trans*port, or processing practices), in order to assure compliance, the manufacturer should analyze samples of the product over the various seasons or relative to other factors to account for variability of nutrient content.

To ensure that label values will accurately represent the nutrient content of food products to consumers and also have a high probability of being in

compliance with nutrition labeling regulations, FDA recommends the calculation of a one-sided 95 percent prediction interval as the most appropriate and the preferred method to use in computing label values (Ref. 108).

Prediction intervals take into account the variability of a nutrient. Mean values do not. A manufacturer of a product, like butter, whose *trans* fat content fluctuates seasonally, would want to analyze samples of *trans* fat during each season and statistically consider using 95 percent prediction intervals to calculate the nutrition label value for *trans* fat. A predicted value on a nutrition label may sometimes indicate a level of a nutrient such as saturated fat at a higher level than is actually in the product, but it will never show a lower level than the product contains. While sometimes predicted values and mean values round to the same nutrient level, products bearing mean values on their nutrition labels have a lower probability of meeting FDA compliance requirements.

VI. Nutrient Content Claims, Health Claims, Disclosure and Disqualifying Levels

In its November 1999 proposal, FDA proposed a definition for the nutrient content claim "*trans* fat free" and proposed limits on the amounts of *trans* fat wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. Several comments to that proposal requested that the final rule define the claim "reduced *trans* fat" or amend the claim "reduced saturated fat" to require a reduction of saturated and *trans* fats combined. To address this issue, the agency reopened the comment period (65 FR 75887) to consider "reduced *trans* fat" and "reduced saturated and *trans* fat" claims.

With regard to the specific definitions, FDA proposed that "*trans* fat free" and "saturated fat free" should be defined as less than 0.5 g *trans* fat and less than 0.5 g saturated fat per reference amount and per labeled serving; "low saturated fat" as 1 g or less of saturated fat and less than 0.5 g of *trans* fat per reference amount and not more than 15 percent of calories from saturated fat and *trans* fat combined; "reduced saturated fat" as at least 25 percent less saturated fat and at least 25 percent less saturated fat and *trans* fat combined; "lean" as 4.5 g or less of saturated fat and *trans* fat combined; and "extra lean" as less than 2 g of saturated fat and *trans* fat combined. In addition, cholesterol claims were allowed only on foods containing 2 g or less of saturated fat and *trans* fat combined, and disqualifying and disclosure levels were set at 4 g or less of saturated fat and *trans* fat combined. FDA did not propose to define "low *trans* fat."

The comments relating to claims were very diverse and indicated strongly opposing views. With regard to the "*trans* fat free" claim, some comments favored the proposed definition, while other comments suggested increasing the saturated fat limit, eliminating the saturated fat limit , or not defining this claim. Similarly, some comments supported the "saturated fat free" claim, while other comments recommended that the *trans* limit be increased to 2 g. For "low saturated fat" some comments favored the proposed definition, while others suggested increasing the *trans* fat limit as high as 2 g. One comment recommended that this claim be less than or equal to 1.5 g of saturated and *trans* fats combined.

A number of comments supported having a "reduced *trans* fat" claim and others were against it. The vast majority of the comments in favor of this claim suggested that *trans* fat be reduced by at least 25 percent, but there was little

agreement on the secondary saturated fat criterion. The comments ranged from no limit on saturated fat, to no increase in the level of saturated fat, a limit of less than or equal to 2 g, or at least a 25 percent reduction. The comments on "reduced saturated" fat were similar to the comments on "reduced *trans* fat" in that there was no agreement on the level of the secondary criterion, i.e., *trans* fat for this claim. In addition, some comments recommended having the claim "reduced saturated and *trans* fats" for greater flexibility, while others opposed such a claim. Of those in favor, some comments recommended a reduction of at least 25 percent in saturated and *trans* fats combined, one comment favored a 33 to 50 percent in saturated and *trans* fats combined, and one comment wanted a 25 percent reduction in saturated fat and a 25 percent reduction in *trans* fat.

Finally, the comments on disclosure and disqualifying levels were equally divergent. Some comments favored the proposed criterion of 4 g or less of saturated and *trans* fats combined, while others recommended a limit of 4 g of saturated fat and 4 g of *trans* fat, or believed that there should be no limit on *trans* fat. One comment stated that *trans* fat thresholds should be incorporated into the criteria defining nutrient content claims and health claims only to the extent that such criteria are necessary to prevent the claim from misleading consumers. The comment stated that this is the approach FDA applied in establishing the saturated fat thresholds for cholesterol content claims in § 101.62(d) and is an appropriate construct for nutrient content claims about *trans* fat.

The objections in the comments against the proposed definitions were generally based on scientific, legal, or economic arguments. Some of the comments believed that the agency is acting in advance of sufficient scientific

justification, while others stated that the agency should have acted sooner. There was disagreement as to whether the adverse effects of *trans* fat are comparable to that of saturated fat. Some of the comments stated that the proposed definitions assume that *trans* fat and saturated fat are "bioequivalent." These comments particularly objected to changing the disclosure and disqualifying level of 4 g of saturated fat to 4 g of saturated and *trans* fat combined (i.e, holding the current level constant and including *trans* fat). These comments argued that the effects of saturated fat and *trans* fat have not been proven to be the same on a gram-for-gram basis and, therefore, should not be treated interchangeably. Other comments stated that there is no scientific evidence showing any adverse effects on serum cholesterol levels or cardiovascular health from *trans* fat in a mixed diet to support FDA's proposed definitions for nutrient content claims.

Other comments argued that the proposed claims should be included in the final rule for public health reasons, while others argued that less restrictive claims would benefit the public health to a greater extent because they would encourage more reformulation. Some of these comments pointed out that the "*trans* fat free" claim, in particular, is impractical because very few foods could meet the proposed criteria and therefore would not be used enough to be helpful.

Several comments asserted that FDA did not meet its burden under the first amendment because the threshold levels proposed by FDA for *trans* fat for certain nutrient content and health claims, which, if exceeded, would prohibit the use of the claims on food and have the effect of restricting the use of specific claims that would be truthful and not misleading. The comments reasoned that FDA could only limit claims where the level of *trans*

fat in a food product would make the claim misleading. Further, the comments reasoned that, before FDA could prohibit a claim, FDA would need to establish that the use of a disclaimer on the label or the disclosure of *trans* fat on the label could not prevent the claim from being potentially misleading.

Economic concerns regarding the proposed nutrient content claims are discussed in section IX of this document.

FDA has carefully reviewed the comments and finds that it has insufficient scientific information at this point in time to support a decision on the appropriate definition for the nutrient content claims discussed in the November 1999 proposal and the December 5, 2000, notice to reopen the comment period. The comments that expressed a preference for a specific threshold level of *trans* fat for various claims did not provide a scientific rationale to support the level. In the past, the development of definitions for nutrient content claims and the establishment of disclosure and disqualifying levels generally have been dependent upon scientific agreement of appropriate quantitative reference values for daily consumption of the nutrient that is the subject of the claim. In proposing nutrient content claims, the agency stated that "With the exception of the term "sugar free" and terms related to caloric levels in foods, the agency has limited the proposed definitions to nutrients for which there are proposed DRVs or RDIs" (56 FR 60421 at 60429, November 27, 1991). The approach of having an appropriate reference value for daily consumption provides a consistent and quantitative basis for defining claims. As stated in section V of this document, the agency does not believe that the current level of scientific evidence supports the establishment of such a value for *trans* fat at this time. Many comments supported this position. As a result of the absence of an appropriate reference value for *trans* fat, the agency has

been hampered in developing an integrated approach that responds to the issues raised in the comments. Accordingly, the agency is withdrawing those sections of the November 1999 proposal pertaining to the establishment of a definition for "*trans* fat free," consideration of "reduced *trans* fat" and "reduced saturated and *trans* fat" claims and limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. FDA plans to continue to evaluate the evolving science and, when the science has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims, it will proceed to do so through a new rulemaking.

VII. Other Issues

(Comment 26) Several comments requested that FDA defer rulemaking on *trans* fat labeling until both FDA and USDA are able to concurrently take this action.

FDA consulted with USDA and both agencies agree that it is important that nutrition labeling rules for both agencies be consistent and that labeling of *trans* fat is necessary to assist consumers in maintaining healthy dietary practices. USDA is considering a similar policy for *trans* fat labeling based on the view that the approach to nutrition labeling should be consistent, but currently does not have a rulemaking on *trans* fat labeling on its regulatory agenda. Because *trans* fat levels are expected to be higher in foods regulated by FDA, as compared to foods under USDA jurisdiction, and because FDA has a citizen petition on the labeling of *trans* fat, FDA has determined that it is necessary to proceed with this final rule based on the public health interest.

FDA notes that it is committed to cooperating with USDA, as needed, on *trans* fat labeling in any future action that USDA may consider.

(Comment 27) Some comments requested that *trans* fat not be used in restaurant food or its use be reduced.

These comments are outside the scope of this rule on the nutritional labeling of *trans* fat. This rulemaking is about *trans* fat labeling and not about whether or not *trans* fat is used in food generally or in particular food products. Although restaurant foods are not required to provide full nutrition labeling, they are required under § 101.10 (21 CFR 101.10), "Nutrition Labeling of Restaurant Foods," to provide information on nutrients that are relevant to any nutrient content claims made. Further guidance on labeling of restaurant foods may be found in "Questions and Answers Volume II, A Guide for Restaurants and Other Retail Establishments" (Ref. 111).

(Comment 28) A number of comments to the November 1999 proposal and the November 2002 notice reopening the comment period of the November 1999 proposal stated that there is a great need for consumer education about *trans* fatty acids and the nutrition label.

FDA agrees that consumer education will be needed as a result of this final rule so that consumers are better able to utilize the new *trans* fat labeling information to assist them in maintaining healthy dietary practices. Since the first edition of "Dietary Guidelines for Americans" in 1980 (Ref. 112), Americans have been advised to avoid too much saturated fat to reduce the risk of heart disease. This message has also been a major factor in the National Cholesterol Education Program, which has been in existence since 1985 (http://www.nhlbi.nih.gov/about/ncep/index.htm). Some success of these educational programs was demonstrated by the third National Health and

Nutrition Examination Survey (Ref. 89) conducted during 1988–94, that showed that the public's intake of saturated fat has declined since the previous survey conducted from 1976–80 (Ref. 113). Also, the 1994–96 CSFII showed a decline in the public's intake of saturated fat since a previous survey conducted in 1989–91 (Ref. 142). Therefore, in introducing new messages about *trans* fatty acids, FDA intends to work with existing public health programs to build upon the extensive work done by them to educate consumers about saturated fatty acids and their relationship to heart health.

The agency also plans to initiate a variety of outreach and consumer education programs about this final rule following publication. Electronic dissemination of this information will be provided at FDA's Web site and briefings will be provided to representatives of a variety of health professionals, government agencies, industry representatives, trade associations, and press and consumer groups so that they can communicate *trans* fat information to their constituencies. To assist in this effort, education and press materials will be developed to facilitate communication to consumers about changes they will see as *trans* fat is added to the nutrition label and how they can use that information in their efforts to maintain a healthy diet.

(Comment 29) A few comments suggested using color coding to help consumers quickly recognize unhealthy products, including those containing *trans* fat. One of the comments mentioned applying this technique to ingredient listing and another comment said that a graphic could show the proportion of saturated, *trans*, polyunsaturated, and monounsaturated fats. The latter comment noted that horizontal color bars were used quite successfully in the introduction of canola oil in the United States.

These comments are outside the scope of this final rule on the nutrition labeling of *trans* fatty acids. The agency notes that manufacturers are free to use color bars on the product label outside of the Nutrition Facts panel (i.e., the box), to illustrate the kinds of fatty acids in their products, provided it is done in a manner that is not misleading, but the panel itself is to be in compliance with this final rule.

(Comment 30) FDA received only one comment in response to the November 1999 proposal to deny the petitioner's request to require that "partially hydrogenated" fat be listed on food labels as "partially saturated" fat (64 FR 62746 at 62762). The comment concurred with the agency's tentative conclusion to deny the request stating that "partially hydrogenated" fat is the most appropriate terminology for use on food label ingredient statements.

The agency concurs with the comment and, accordingly, is denying this request.

(Comment 31) Although a great many comments supported CSPI's petition in general, these comments did not specifically address the petitioner's request to limit "vegetable oil" claims to foods that are low in saturated and *trans* fats combined.

In the November 1999 proposal, the agency referred to § 101.65(c)(3), which states, in part, that a claim "that a food is made only with vegetable oil is a claim that the food is low in saturated fat," and tentatively concluded that the petitioner's request was being addressed by the action taken in the proposed rule to limit the amount of *trans* fat in foods bearing "low in saturated fat" claims (64 FR 62746 at 62762). However, in this final regulation those sections of the proposed rule pertaining to limiting the amount of *trans* fat in foods making a "low in saturated fat" claim are being withdrawn.

Therefore, the agency is not restricting "vegetable oil" claims as proposed or as petitioned at this time.

As discussed in section VI of this document, FDA plans to proceed with a new rulemaking pertaining to limits on the amount of *trans* fat in claims relating to saturated fat when the science on *trans* fat has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims.

VIII. Effective Date

In the November 1999 proposal, the agency proposed that any final rule that may issue based upon the proposal become effective in accordance with the uniform effective date for compliance with food labeling requirements that is announced by notice in the **Federal Register** and that it not be sooner than 1 year following publication of any final rule based on the proposal. Also, the agency said it will not object to voluntary compliance immediately upon publication of the final rule.

(Comment 32) FDA received several comments about the effective date for a final rule. One comment stated that the proposed effective date was appropriate while a few other comments recommended that it be sooner than proposed. Several comments suggested that the effective date be 24 months after publication of the final rule or January 1, 2004, whichever comes later. Some comments, however, requested that the effective date be extended several years (e.g., 4 to 7 years) for small businesses. These comments stated that it was important for small businesses to be able to phase in the cost associated with the new label requirements so that they have extra time to absorb the costs of these changes. Many small manufacturers reported that they have significant inventories of labels. Also, smaller manufacturers indicated that

they would incur costs including loss and disposal of obsolete packaging inventories, product in obsolete packages, and new printing plates. These small businesses believe that a longer compliance period would allow these companies to more easily manage their inventories and phase in the *trans* fat labeling requirements along with other scheduled labeling revisions. This will help minimize unnecessary labeling costs and costs passed on to consumers. At least one comment requested that the effective date be one year after establishment of an official AOAC method for measuring *trans* fatty acids in complex food matrices.

To minimize the need for multiple labeling changes and to provide additional time for compliance by small businesses to allow them to use current label inventories and phase in label changes, the agency is setting the effective date at January 1, 2006, the next uniform effective date following publication of this rule. This allows firms more than 2 years to implement this final rule providing some regulatory relief and economic savings for small businesses. Extending the effective date for products containing *trans* fat would delay the benefits of this rule to the public health.

The agency notes that there are several methods for measuring the amounts of *trans* fat in food products including but not limited to AOAC Method 996.06, as modified (17th edition of the "Official Methods of Analysis of the AOAC International") (Refs. 105 and 106). Consequently, the agency does not believe that there is any need to extend the effective date because of the lack of appropriate methodology.

Although the effective date of the final rule is some time away, FDA encourages manufacturers to have new labels printed that are in compliance with these final rules so they may be used as soon as current inventories are

exhausted to ensure a smooth and timely changeover. The agency will not object to voluntary compliance immediately upon publication of the final rule.

IX. Final Regulatory Impact Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, Office of Management and Budget (OMB) has determined that this final rule is a major rule for the purpose of congressional review.

A. The Current Situation and the Need for This Regulation

Current nutrition labeling regulations do not allow manufacturers to disclose information about *trans* fat content of their products in the Nutrition Facts panel of product labels. The regulation, in § 101.9(c) reads, in part, "No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label." Some of the nutrients listed are total fat, saturated fat, polyunsaturated fat (voluntary), and monounsaturated fat (voluntary). Prior to publication of this final rule *trans* fat was not included as either mandatory or voluntary, and therefore, no information about *trans* fat could have been included in the Nutrition Facts panel.

As explained in the November 1999 proposal and in section IV of this document, there is a scientifically established link between the consumption of *trans* fat and CHD. As described in table 1 of this document, for purposes of economic analysis, FDA estimated *trans* fat intake based on dietary intakes reported in a national food consumption survey. FDA estimates that average *trans* fat intake from partially hydrogenated fat is about 2.03 percent of energy, and average total *trans* fat intake, including *trans* fat of ruminant origin, is about 2.55 percent of energy. Because *trans* fat increases serum LDL–C ("bad" cholesterol), reducing *trans* fat intake reduces CHD risk. The amount of risk reduction depends on what replaces *trans* fat in the diet (64 FR 62746 at 62768 to 62770). For example, as shown later in this section, reducing *trans* fat intake by 0.1 percent reduces CHD risk by 0.072 to 0.163 percent.[1] CHD is a common

[1] Using Method 1 (LDL–C), described later in section IX.E, and the factors shown in tables 8 and 9 below, replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.072 percent when replaced with the same percent of energy from half *cis*-monounsaturated fat and half saturated fat (-0.1 x 0.74 x 0.7 x 1.4 = -0.072) and by 0.163 when replaced with half *cis*-monounsaturated fat and half *cis*-polyunsaturated fat (-0.1 x 1.66 x 0.7 x 1.4 = -0.163).

disease in the general U.S. population, with about 1.1 million heart attacks annually, 40 percent of them fatal (Ref. 134). Therefore, a small decrease in risk corresponds to a large number of heart attacks and deaths prevented. Thus, as shown later in this section, reducing *trans* fat intake by about 0.04 percent of energy (projected to decrease CHD risk by about 0.05 percent), prevents approximately 600 heart attacks per year, including 200 fatal heart attacks. Preventing these heart attacks is valued at $4.1 billion per year (present value discounted at 7 percent).

Although the effect of *trans* fat on LDL–C and CHD risk is the primary basis for *trans* fat labeling, *trans* fat may also increase CHD risk by lowering high-density lipoprotein cholesterol (HDL–C) ("good" cholesterol). In a second method for estimating the health benefits of *trans* fat labeling, the expected changes in LDL–C and HDL–C can be considered together (64 FR 62746 at 62768 to 62770). For example, as shown later in this section, each 0.1 percent of energy decrease in *trans* fat intake reduces CHD risk by 0.237 to 0.293 percent.[2] Thus, as shown later in this section, reducing *trans* fat intake by about 0.04 percent of energy (projected to decrease CHD risk by about 0.1 percent), prevents approximately 1,200 heart attacks, including 480 fatal heart attacks, annually, valued at $8.3 billion per year (present value discounted at 7 percent).

This final regulation is needed to amend existing regulations so that manufacturers will be able to provide important health-related information to consumers regarding the amount of *trans* fat in food products.

[2] Using Method 2 (LDL–C and HDL–C), replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.237 percent when replaced with the same percent of energy from half *cis*-monounsaturated fat and half saturated fat (-0.1 x -0.47 x -2.5 x 1.4 = -0.165 and -0.072 plus -0.165 = 0.237) and by 0.293 when replaced with half *cis*-monounsaturated fat and half *cis*-polyunsaturated fat (-0.1 x -0.37 x -2.5 x 1.4 = -0.130 and -0.163 plus -0.130 = -0.293).

FDA believes that the requirements of this final rule will provide consumers with information they need so that they may consider the amount of *trans* fat in products in their food purchasing decisions. Increased consumer attention to *trans* fat content because of nutrition labeling may also provide an incentive to food manufacturers to reduce the amount of *trans* fat in their products.

B. Regulatory Alternatives

In the analysis of the proposed rule, FDA listed a number of regulatory alternatives regarding *trans* fat, including: (1) Take no new regulatory action; (2) take the proposed regulatory action; (3) propose to permit the voluntary labeling of *trans* fat and to permit *trans* fat nutrient content claims; (4) alter the proposed regulatory action—propose reporting of *trans* fat on a separate line below saturated fat; (5) alter the proposed regulatory action—propose to report *trans* fat differently than in the proposal; (6) expand the proposed regulatory action—propose "low *trans* fat" and "reduced *trans* fat" claims; (7) expand the proposed regulatory action—propose labeling at food service establishments. We evaluated these regulatory alternatives in the economic discussion of the proposed rule, although we lacked sufficient data to evaluate all of the options quantitatively. FDA received no comments on the economic discussion of these alternatives, so we do not include them in this document. In addition to the alternatives described in the proposed rule, FDA considered and asked for comments on a proposed required footnote. Because the agency is withdrawing the proposed requirement for a footnote and intends to ask for comments in an ANPRM published elsewhere in this issue of the **Federal Register**, we will not estimate the costs and benefits of that option in this document.

C. Changes Resulting From This Rule

As stated in the analysis to the proposed rule (64 FR 62746 at 62764), to estimate the impacts of this rule, FDA is following the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA is estimating: (1) The changes in *trans* fat intakes that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits.

1. Changes in Existing Labeling Regulations

This final rule authorizes the mandatory declaration in the nutrition label of the amount of *trans* fat present in foods. According to this final rule, the amount of *trans* fat must be on a separate line immediately under the amount of saturated fat, but it will not include a % DV that is required for some of the other mandatory nutrients, such as saturated fat. This change to the existing regulations will increase the information available to consumers that they can use to maintain a healthy diet. It will also change the constraints and incentives faced by producers of food.

The final rule will increase the information provided to consumers on food packages. This change in the nutrition label will reduce the cost to consumers of obtaining information on the *trans* fat content of food. FDA anticipates that, once the rule takes effect, consumers will use information on the Nutrition Facts panel to adjust their purchasing practices among foods, consistent with their consumption preferences.

The final rule will also change the incentives and constraints that food producers face in manufacturing and marketing their products. Because these provisions will not be effective until months after publication of the final rule, food manufacturers can use the time between publication of the final rule and its effective date to study the requirements of the rule and the composition of their products, to anticipate the response of consumers and competitors to the new information, to change the labeling, and possibly to change the composition of their existing food products. Even after the effective date of the rule, food manufacturers will observe the response of consumers to the information on *trans* fat, and some may develop and market new products with less *trans* fat than similar existing products.

FDA assumes that producers will decide whether or not to change the composition of existing products on a product-by-product basis, depending on expected private returns. They will choose to reformulate the existing products when the expected private benefits exceed the expected private costs of reformulating the products. In other words, if a product is expected to lose market share without reformulation because of the new disclosure, then manufacturers will compare the private costs from decreased sales to the cost of reformulation.

2. Anticipated Changes in *Trans* Fat Intake

FDA anticipates that, taken together, changes in food purchases by consumers and reformulation by producers in response to this rule will result in an overall decrease in *trans* fat intake in the U.S. population. In the November 1999 proposal, FDA developed four scenarios to demonstrate potential quantitative changes in *trans* fat intake (64 FR 62746 at 62767). FDA

also estimated the current *trans* fat intake of the population as a starting point for its scenarios for projected intake changes.

a. *Revised estimate of current trans fat intake.* In section IV of this document, FDA discussed the uncertainties associated with estimates of *trans* fat intake from: (1) National food consumption survey, (2) national disappearance data, and (3) food frequency questionnaires done in observational studies of U.S. population groups. Although there are uncertainties associated with each type of estimate, FDA chose estimation of *trans* fat intake based on a national food consumption survey as most suitable for use in this economic analysis. Estimates of intake based on national disappearance data generally overestimate intake dues to losses in processing and use, and food groups derived from disappearance data correspond to commodities rather than to foods as consumed. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on national disappearance data. Estimates of *trans* fat intake based on food frequency questionnaires may have the advantage of having been validated versus biomarkers such as *trans* fat content of adipose tissue. Such estimates are suitable for their intended use in ranking and classifying *trans* fat intake of subjects in observation studies. However, food frequency questionnaires are not necessarily designed to provide accurate absolute (numerical) intake estimates. As described in section IV of this document, available estimates of *trans* fat intake from food frequency questionnaires tend to underestimate *trans* fat intake compared with estimates of *trans* fat intake from a national food consumption survey. Additionally, the available food frequency results pertain to the intake of specific U.S. population groups in the observation studies, not to the overall U.S.

population. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on food frequency questionnaires done in observational studies. One disadvantage of an estimate based on a national food consumption survey is that, as described in section IV, food intake is generally under-reported in consumption surveys. Therefore, intake of *trans* fat, in grams, estimated from a national consumption survey is likely to underestimate actual intake. However, it is likely to underestimate actual intake of *trans* fat to a lesser extent from National Consumption Survey data than from data based on the intake of *trans* fat from food frequencies done in observation studies. Additionally, intake of *trans* fat, as a percent of total energy, from a national consumption survey is more likely to be an unbiased estimate (Ref. 26).

As described in the November 1999 proposal (64 FR 62746 at 62765), information on *trans* fat content of foods is limited, and there have been few estimates of *trans* fat intake based on national dietary surveys using food records or recalls. As described in section IV of this document and in the November 1999 proposal (64 FR 62746 at 62752 and 62765), an available estimate by Allison et al. (Ref. 26), based on CSFII 1989–91, reported mean *trans* fat intake of 5.3 g/day (d) (2.6 percent of energy). However, for the purposes of economic analysis, FDA needed to estimate the mean intake of *trans* fat from specific food groups. Therefore, in the November 1999 proposal, FDA indirectly estimated *trans* fat intake based on a report from the Research Triangle Institute (RTI) (Ref. 73). The RTI report used a special 1995 USDA database of *trans* fat content of foods (Ref. 40), together with the mean intake of food groups from USDA's CSFII 1994–96, and matched the CSFII 1994–96 food groups with Standard Industrial Classification (SIC) Codes for food

product categories. FDA limited its estimate to foods with *trans* fat from partially hydrogenated fats and oils (64 FR 62746 at 62765). (Although *trans* fat does occur naturally in dairy foods, it is generally present in dairy products at less than 0.5 g *trans* fat per serving, and therefore most dairy products would not have been affected by the November 1999 proposal (64 FR 62746 at 62775)).

In the November 1999 proposal, FDA estimated that current average *trans* fat intake from hydrogenated fat was 2.91 percent of energy (calories) for adults, which is about 7.62 g/d for men and 5.54 g/d for women (Ref. 73 and 64 FR 62746 at 62765). Among food product categories, average *trans* fat intake of adults, as a percent of energy, was: margarine, 0.39 percent; bread/cake, 0.67 percent; cookies/crackers, 0.98 percent; other food groups, 0.87 percent. The estimated intake of *trans* fat from margarine included FDA's adjustment based on the assumption that approximately 30 percent of margarines currently on the market had already been reformulated to remove *trans* fat.

(Comment 33) Comments generally agreed that FDA's estimate of current *trans* fat intake was reasonable and in the range of other estimates of *trans* fat intake. Comments from the margarine industry agreed with FDA's overall estimate of *trans* fat intake from margarine but stated that FDA had overestimated the percent of margarines (30 percent) that had already been reformulated to remove *trans* fat. One comment indicated that the proportion of margarines with less than 0.5 g *trans* fat per serving is about half of FDA's estimate, or 15 percent of margarines. Some comments pointed out the importance of *trans* fat intake from food groups that were not itemized separately in FDA's summary table, including chips and snacks and French fried potatoes. Because FDA had restricted its estimate to *trans* fat intake from

partially hydrogenated fats and oils, some comments requested clarification regarding whether naturally-occurring *trans* fat of ruminant origin would be regulated by the provisions of the proposed rule. One comment from a manufacturer agreed with FDA that the USDA *trans* fatty acid database contains relatively few foods. This comment recommended that a large database be developed of *trans* fat food values that have been analyzed using standardized methods, and that the database be used to establish reference or "normative" intake data on *trans* fat in the U.S. population. The comment stated that this information would be helpful in developing a Daily Value for *trans* fat intake. A comment from the dressings and sauces industry disagreed with FDA's statement that "some salad dressings contain substantial amounts of *trans* fatty acids" (64 FR 62746 at 62752). The comment stated that the oils used in dressing and sauce products contain less than one percent *trans* fatty acids. Additionally, according to the comment, the contribution of *trans* fat of ruminant origin is negligible in dressings and sauces that contain dairy products, as demonstrated in the reference cited by FDA regarding *trans* fat in salad dressings (Refs. 29 and 30).

FDA's original estimate that about 30 percent of margarine had been reformulated to remove *trans* fat was based on an informal market survey in the Washington, DC area (Ref. 80 and 64 FR 62746 at 62781). FDA accepts the comment's estimate that 15 percent of margarines currently on the market contain less than 0.5 g per serving. In its own estimate of total intake, FDA did include the contribution to average *trans* fat intake of other food groups containing partially hydrogenated fat, such as chips and French fried potatoes. These food groups were itemized in the RTI report (Ref. 73) but FDA summarized them under "All other" in the November 1999 proposal.

In response to the comments requesting clarification about whether naturally-ocurring *trans* fat of ruminant origin would be regulated by this rule, FDA reiterates that this final rule applies to all FDA-regulated foods and covers all fatty acids that meet the regulatory definition of "*trans* fatty acids," regardless of origin. Naturally occurring *trans* fat in dairy products and in ruminant meat (e.g., meat from cows and sheep) present in FDA-regulated food products will be subject to this rule. FDA did not include *trans* fat of ruminant origin in its original intake estimate in the November 1999 proposal because, in these products, *trans* fat is generally present at less than 0.5 g per serving and declaration of the amount of *trans* fat in these products would not have been required by the November 1999 proposal. As noted later in this section, we have revised our estimate of *trans* fat intake and extended our revised estimate to include *trans* fat of ruminant origin. Although FDA agrees with the comment stating that development of a large database of *trans* fat food values would be beneficial, database development is beyond the scope of the present rulemaking. FDA agrees with the comment regarding the *trans* fat content of dressing and sauces and acknowledges that FDA's earlier statement about *trans* fat in salad dressings (64 FR 62746 at 62752) was inaccurate. However FDA's earlier statement was part of a general summary of possible limitations of data regarding *trans* fat intake of the population, and was not incorporated into FDA's estimates of *trans* fat intake in the November 1999 proposal. As noted previously, FDA based its estimates of *trans* fat intake on the special 1995 USDA database of *trans* fat content of selected foods.

As described previously in this section, although there are uncertainties associated with each type of estimate, FDA chose estimation of *trans* fat intake based on a national food consumption survey as most suitable for use in this

economic analysis. In reevaluating its November 1999 *trans* fat intake estimate based on a national survey, CSFII 1994–96, FDA notes that the CSFII 1994–96 food group categories used to generate the estimate were very broad (Refs. 73 and 114) and the match between the broad CSFII food group categories and the SIC Codes was not always exact. Recently, USDA has published more detailed tables of food group intake for CSFII 1994–96 (Ref. 115). FDA has used the new tables to recalculate its estimate of average *trans* fat intake in the United States. For clarity, FDA now includes the itemized *trans* fat intake for the various food groups rather than creating a summary category for "All other." FDA has also extended its estimate to incorporate *trans* fat of ruminant origin. FDA has estimated the intake of *trans* fat from margarine from the USDA intake data, without assumptions regarding the percent of margarine that may have been reformulated to remove *trans* fat. We will describe our assumptions about current margarine reformulation in later sections of this document.

The revised estimate of average *trans* fat intake of adults in the United States for this economic analysis is shown in table 1 of this document. The revised estimate is slightly lower than that in the November 1999 proposal. Table 1 shows that average *trans* fat intake from partially hydrogenated vegetable oils is about 5.36 g/d for men and 3.89 g/d for women, or about 2.03 percent of energy. Adding the *trans* fat of ruminant origin gives an overall total *trans* fat intake of 6.86 g/d for men and 4.78 g/d for women, about 2.55 percent of energy. Major sources of *trans* fat intake as a percent of energy include margarine, 0.42 percent; cake and related products, 0.61 percent; cookies and crackers, 0.25 percent; fried potatoes, 0.21 percent; chips and snacks, 0.12 percent; and household shortening, 0.11 percent.

TABLE 1.—AVERAGE *Trans* FAT INTAKE OF U.S. ADULTS FROM FOOD GROUPS

CSFII 94–96[1]	Men	Women	All	All
Mean daily energy intake, kcal[2]	2455	1646	2058	
Mean daily *trans* fat intake[3 4]				
Food group	Grams	Grams	Grams	% of energy
Hydrogenated products				
Total yeast bread	0.475	0 330	0 404	0.177%
Cakes, pies, doughnuts, sweet rolls, biscuits, muffins, quick breads, pancakes, waffles, tortillas	1 607	1 163	1 391	0.607%
Cookies, crackers	0.624	0.515	0.571	0.249%
Ready to eat breakfast cereal	0 093	0.074	0 084	0.037%
French-fried, home-fried potatoes	0.635	0.332	0.486	0 213%
Potato chips, corn chips, popcorn	0 345	0.215	0 281	0.123%
Pourable and mayo type salad dressing	0.181	0.136	0.159	0.069%
Total candy containing chocolate	0 048	0.040	0.044	0.019%
Total margarine	1.072	0 859	0.967	0.423%
Household shortening	0.277	0 222	0.250	0.109%
Total hydrogenated products	5.357	3.886	4.637	2.026%
Animal products				
Total milk, including on cereal	0.125	0.085	0.105	0.046%
Ice cream and ice milk	0.092	0.057	0.075	0.033%
Total cheese and cottage cheese	0.227	0.148	0.188	0.083%
Total beef, ground and not ground	0 569	0.319	0.447	0.195%
Total frankfurter and lunch meat	0.360	0.188	0.276	0.121%
Total fluid and sour cream	0.061	0 044	0.052	0.023%
Total butter	0.071	0.049	0.060	0.026%
Total animal products	1.505	0.890	1.203	0.527%
Total all products	6.862	4.776	5.840	2.553%

[1] Continuing Survey of Food Intakes of Individuals, 1994–1996
[2] kcal: kilocalories
[3] Source of *trans* fat content of foods: Ref. 40.
[4] Source of food intake data: Smiciklas-Wright H., D.C. Mitchell, S.J. Mickle, A.J. Cook and J D. Goldman. Foods Commonly Eaten in the United States, Quantities per Eating Occasion and in a Day, 1994–1996. U.S. Department of Agriculture NFS Report No 96–5, pre-publication version, 2002. www.barc.usda.gov/bhnrc/foodsurvey/Products9496.html.

The revised estimate of *trans* fat intake based on CSFII 1994–96 and shown in table 1 is slightly lower than the estimate in the November 1999 proposal (64 FR 62746 at 62765). Table 1 shows that average *trans* fat intake from partially hydrogenated vegetable oils is about 5.36 g/d for men and 3.89 g/d for women, or about 2.03 percent of energy. Adding the *trans* fat of ruminant origin gives an overall total *trans* fat intake of 6.86 g/d for men and 4.78 g/d for women, about 2.55 percent of energy. Major sources of *trans* fat intake as a percent of energy include margarine, 0.42 percent; cake and related products, 0.61 percent; cookies and crackers, 0.25 percent; fried potatoes, 0.21 percent; chips and snacks, 0.12 percent; and household shortening, 0.11 percent. For comparison, FDA also calculated the *trans* fat intake based on CSFII 1989–91, using the same method as for the estimate based on CSFII 1994–96 (Ref. 116 and 117). The overall total *trans* fat intake from CSFII 1989–91 is 6.47 g/d for men, 4.51 g/d for women and 5.32 g/d for all adults, or

2.71 percent of energy (not shown in table 1), very similar to the 6.86 g/d for men and 4.78 g/d for women and 5.84 g/d for all adults, or 2.55 percent of energy intake based on CSFII 1994–96 (table 1 of this document) (Ref. 116). FDA's estimates of 2.55 percent of energy from *trans* fat based on CSFII 1994–96 and 2.71 percent of energy based on CSFII 1989–91 can be compared with other available estimates from national food consumption surveys. FDA's estimates are very similar to the intake estimated by Allison et al. based on CSFII 1989–91 (Ref. 26), using a different method. As described in the November 1999 proposal, Allison et al. reported that average *trans* fat intake for persons age 3 and older was 2.6 percent of energy, or 5.3 g/d (64 FR 62746 at 62752 and 62765).

Allison et al. linked the special 1995 USDA database of *trans* fat content of foods to the food intake reported by each individual in CSFII 1989–91 (Ref. 26). They also separated the ingredients in food mixtures, so that the *trans* fat content of the ingredients could be included in the total intake. These researchers reported the *trans* fat intake for various age and gender groups in the United States, but did not report the amount of *trans* fat contributed by various foods and food groups. To make its estimate, FDA began with USDA reports of average intake of food groups in CSFII 1989–91 and 1994–96 (Refs. 115 and 117). In its reports, USDA also separated the ingredients in food mixtures. For example, in CSFII 1994–96, USDA found that the average intake of margarine reported separately by survey participants was 2.8 g/d. However, when margarine, used as an ingredient in other foods, was added to the total, the average margarine intake rose to 7.0 g/d. FDA then linked the average intake of the food groups with the *trans* fat content of foods from the special 1995 USDA database (Ref. 40) to give the *trans* fat intake estimate in table

1 of this document. The similarity of the estimates of FDA and of Allison et al. can be explained by use of common data—the CSFII intake report and the 1995 USDA *trans* fat database. Linking the two data sets resulted in comparable overall *trans* intake, whether linked at the level of each individual's intake by Allison et al., or linked at the level of average intake of food groups by FDA.

FDA's estimates are also similar to a recently-published estimate from another national food consumption survey, the National Health and Nutrition Examination Survey III (NHANES III), 1988–94 (Refs. 152 and 153). The estimate from NHANES III for mean *trans* fat intake for age 20 to 59 was 5.6 g/d or 2.2 percent of energy (mean energy intake was 2,325 kcal/d, and (5.6 g/d x 9 kcal/g x 100)/2,325 kcal = 2.2 percent of energy).

b. *Projected change in trans fat intake.* In the November 1999 proposal, we developed four scenarios of projected changes in *trans* fat intake due to labeling. Scenario 1 demonstrated the effect of the hypothetical removal of all of the *trans* fat originating from partially hydrogenated fats and oils, corresponding to a decrease of 2.91 percent of energy from *trans* fat. Scenarios 2 through 4 predicted three possible levels of product reformulation, together with an estimate of consumer behavior. We estimated that *trans* fat intake would have decreased by 0.58 percent of energy, 0.50 percent of energy and 0.42 percent of energy in Scenarios 2, 3 and 4, respectively (64 FR 62746 at 62767). For each scenario, the full health benefits would have been realized years after the rule took effect: 10, 8, and 3 years after the effective date for Scenarios 2, 3, and 4. These time periods included the time for reformulation and the 3 years that would have passed before changes in diet would have begun to reduce the risk of CHD.

Consumer awareness

(Comment 34) Several comments suggested that FDA overstated consumer response to the proposed change to food labeling. Some comments said that a footnote might be ignored. Some comments said that consumers rarely look at any nutrition information beyond calories and total fat and that consumer concerns about fat have dwindled. One comment argued that consumers have not significantly altered their dietary habits because of the implementation of the 1990 amendments. One comment stated that educated consumers probably already know enough to look for and avoid *trans* fat. There was also one comment arguing that shelf labeling is more likely to attract consumer attention than are product labels, and the use of shelf labeling is probably more prevalent than that of product labels. One comment stated that FDA has underestimated consumer awareness of *trans* fatty acids. Another comment stated that consumer awareness is likely to increase as *trans* fat dietary recommendations accumulate and consumer education devotes more attention to *trans* fat.

FDA is not going forward with the proposed asterisk for saturated fat and footnote listing the amount of *trans* fat. Instead, this final rule requires *trans* fat to be listed on a separate line immediately below saturated fat. Consumers who look at the Nutrition Facts panel for information on total fat and its fatty acid subcomponents are likely to notice the information on *trans* fat.

In the November 1999 proposal, FDA used results of earlier research and estimated that direct consumer choice in response to *trans* fat labeling would result in a 1 percent decrease in *trans* fat intake (64 FR 62746 at 62766). This final rule requires that the amount of *trans* fat be declared in nutrition labels on a separate line immediately under the line for saturated fat. This placement

of *trans* fat is more prominent than the footnote specified in the November 1999 proposal and may be more readily noticed by consumers. In the November 1999 proposal, the amount of *trans* fat was to be included in the amount and % DV declared for saturated fat. This association of *trans* fat with saturated fat, which also may have assisted consumers in using the information on *trans* fat, is absent in this final rule. Also, as a result of this final rule, consumer response to *trans* fat information will be based solely on the declaration of the amount of *trans* fat in grams. As discussed in section V of this document, there will not be information on a % DV for *trans* fat. In the November 1999 proposal, the agency proposed to define the nutrient content claim for "*trans* fat free" and also proposed that the amount of *trans* fat be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. As explained in sections V and VI of this document, this final rule does not establish definitions for nutrient content claims about *trans* fat and does not place *trans* fat limits on claims regarding saturated fat, cholesterol or other nutrients. In summary, the declaration of *trans* fat in this final rule is prominent and straightforward. This feature of the final rule may tend to increase the magnitude of consumer response to the *trans* fat information. However, the provisions of this final rule also do not link *trans* fat with saturated fat or with a % DV for *trans* fat and do not change existing regulations regarding claims. The absence of these features in the final rule may tend to decrease the magnitude of consumer response to the *trans* fat information.

Based on previous research, the November 1999 proposal projected a 1 percent decrease in *trans* fat intake from direct consumer choice in response to *trans* fat labeling (64 FR 62746 at 62766). This overall 1 percent decrease

in *trans* fat intake could be thought of as a 2.2 percent decrease in *trans* fat intake by the 45 percent of consumers shown in previous research to use food labels to make purchase decisions (Refs. 68 and 74) (64 FR 62746 at 62766).

In the process of evaluating these comments about consumer awareness, FDA has identified additional data relevant to these issues. In the 1999 Discovery Health survey, 66 percent of those responding to the survey knew that saturated fat was related to disease and 31 percent knew that partially hydrogenated fat was related to disease (Ref. 118). In the 2001–2002 Consumer Attitudes About Nutrition survey, 83 percent of respondents reported that saturated fat is unhealthy, 46 percent reported that *trans* fat is unhealthy and 44 percent reported that hydrogenated fat is unhealthy (Ref. 135). These results indicate that survey respondents were about half as likely to know that partially hydrogenated fat was "unhealthy" or related to disease as to know that saturated fat was related to disease. If these surveys are representative of the population, this indicates a significant level of awareness of the health effect of partially hydrogenated fat, and its component, *trans* fat, even though consumers have very little easily obtainable information on *trans* fat and even though nutrition education efforts, until very recently, have focused on saturated fat to the exclusion of *trans* fat. Once nutrition education efforts include *trans* fat in their messages and once consumers have information on nutrition labels about *trans* fat content, consumer awareness of the relationship between *trans* fat and heart disease will increase. Another recent study, by Kim et al., estimated that food label use has a large effect on nutrient intake. (Ref. 119) This study reported that 73 percent of individuals surveyed use nutrition labels and look for information on saturated fat.

In the study by Kim et al., 73 percent of individuals surveyed who use nutrition labels and look for information on saturated fat had 15 percent lower saturated fat intake than those who did not use nutrition labels. This corresponds with an overall 11 percent decrease (0.15 x 73 percent = 11 percent) in saturated fat intake because of nutrition labeling. Thus, the study by Kim et al. gave a high estimate of an 11 percent decrease in saturated fat intake because of nutrition labeling and FDA's earlier research gave a low estimate of a 1 percent decrease in saturated fat intake.

The Discovery Health study and the Consumer Attitudes About Nutrition survey indicated that consumer awareness of a nutrient-disease relationship involving *trans* fat was about half as prevalent as consumer awareness of a nutrient-disease relationship involving saturated fat. Accounting for the lower prevalence of awareness of the nutrient-disease relationship for *trans* fat, would reduce, by about one-half, the estimates for decreases in saturated fat intake. This would give a high estimate of a 5.5 percent decrease and a low estimate of a 0.5 percent decrease in *trans* fat intake because of labeling.

The estimates for decreases in *trans* fat intake due to nutrition labeling may also be affected by the features of this final rule. As noted previously, the prominence of the declaration of *trans* fat in this final rule may tend to increase the magnitude of consumer response to the *trans* fat information. However, the magnitude of consumer response to the *trans* fat information may decrease because there is no link with saturated fat or with a % DV and there are no changes in existing regulations regarding claims. Recognizing that different features of this final rule may tend to either increase or decrease consumer response to the *trans* fat information, FDA acknowledges considerable uncertainty in incorporating the features of this final rule into

its estimate of the consumer response to *trans* fat labeling. One possibility is that the increased and decreased responses related to features of the rule will be about equal and will cancel each other out. This would leave a high estimate of 5.5 percent decrease and a low estimate of a 0.5 percent decrease in *trans* fat intake as discussed above. However, for the purpose of this final analysis, FDA has chosen a very low estimate of consumer response to the new label. FDA is using an estimate even lower than the low estimate above: a decrease of 0.1 percent of *trans* fat intake. The actual change that occurs may be larger. However, FDA chose this amount so as not to overestimate benefits of this rule. To the extent that actual consumer response is higher than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

i. *Margarine reformulation.* In the November 1999 proposal, in scenarios 2 through 4, FDA estimated that 30 percent of margarine products had already been reformulated to eliminate *trans* fat, and that all of the remaining margarine products would be reformulated to remove *trans* fat by the effective date for *trans* fat labeling.

(Comment 35) A comment stated that FDA had overestimated the proportion of margarine that had already been reformulated and said that the actual amount was about 15 percent of margarine products. Several comments disagreed with FDA's estimate that all margarine would reformulate by the effective date for *trans* fat labeling. These comments noted that reformulation is very expensive, requires a long time to accomplish, and would, under certain circumstances, require the use of more expensive inputs. Other comments stated that private benefits of reformulating margarine products would not exceed the private costs for manufacturers unless the margarine products could make nutrient content claims. These comments gave a number of examples

to demonstrate that even reformulated margarines were not likely to be able to comply with the proposed definitions for nutrient content claims.

FDA accepts the comment about current margarine products. For this analysis, FDA estimates that about 15 percent of margarine has already been reformulated to remove *trans* fat. In response to the comments about projected margarine reformulation, FDA notes that the analysis for the November 1999 proposal did include the cost of reformulation and the time needed for reformulation. In that analysis, FDA did not include higher ingredient costs for margarine reformulation, because the price of reformulated margarine products that are already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, in response to the comments, FDA acknowledges that, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs.

As noted earlier regarding consumer response to *trans* fat labeling, the declaration of *trans* fat in this final rule is prominent and straightforward. This feature may tend to increase the incentives for manufacturers to reformulate their products to be lower in *trans* fat. However, the provisions of this final rule also do not link *trans* fat with saturated fat or with a % DV for *trans* fat and do not change existing regulations regarding claims. The absence of these features may tend to decrease the incentives for manufacturers to reformulate their products to be lower in *trans* fat. Therefore, in response to the comments regarding projected margarine reformulation, FDA recognizes that different features of this final rule may tend to either increase or decrease the incentive for reformulation.

Although FDA acknowledges considerable uncertainty in the likelihood of additional margarine reformulation, FDA is aware of evidence suggesting that at least some margarine products are likely to reformulate in response to *trans* fat labeling. As stated in the analysis for the proposed rule, in several European countries, the actual, demonstrated market response to consumer concern about *trans* fat is that margarine products have been reformulated to reduce or eliminate *trans* fat (64 FR 62746 at 62781) (Refs. 102, 124, 125, and 127). Also, many people who now consume margarine products do so in order to consume a more heart-healthy product than butter. Because the rule would require the prominent declaration of the amount of *trans* fat on a separate line below saturated fat, these margarine consumers are likely to search for margarine products with lower levels of both saturated fat and *trans* fat. Additionally, publicity generated about the issue by consumer groups and the media has highlighted margarine as a source of *trans* fat and has given prominent attention to reformulated margarine products. As more margarine products are reformulated, consumer groups may shift their focus to those remaining margarine products that have not reformulated. This suggests that with sufficient information on *trans* fat content consumers are likely to pressure margarine producers to reduce *trans* fat. This consumer pressure will generate some competitive pressures among margarine producers to reduce *trans* fat content even in the absence of nutrient content claims.

In response to comments received, because of the absence of *trans* fat claims in this rule, and recognizing the uncertainty, FDA is using a low estimate of margarine reformulation in this final rule. FDA estimates that reformulation will reduce the *trans* fat content of margarines as a whole by 10 percent due to *trans* fat labeling. Because the *trans* fat in margarine accounts

for about 0.36 percent of energy intake, this reduction corresponds to a decrease in *trans* fat intake of 0.036 percent of energy. The actual decrease may be larger, but FDA chose this lower amount so as not to overestimate benefits of this rule. The additional 10 percent margarine reformulation will mean that, including previous reformulations, about 23 percent of *trans* fat will have been removed from margarine. This estimated reduction is far lower than the 100 percent reduction seen in several European countries. The estimated 10 percent reformulation has the advantage of being an underestimate. To the extent that more *trans* fat is removed from margarine than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

ii. *Reformulation of other products.* In two scenarios in the November 1999 proposal, FDA projected that some baked products would be reformulated to remove *trans* fat (64 FR 62746 at 62767). In that analysis, the baked products were separated into two categories corresponding to SIC codes: breads, cakes and similar products (SIC code 2051) and cookies and crackers (SIC code 2052). Considering the *trans* fat contributions of the two categories of baked goods (64 FR 62746 at 62765), the overall projected reformulation of baked goods corresponded to a 5 percent reduction in *trans* fat intake in scenario 3 and a 10 percent reduction in scenario 2.

(Comment 36) A number of comments stated that FDA had overestimated the proportion of baked goods products that would reformulate or the proportion of *trans* fat that could realistically be removed from baked goods by reformulation. Some comments noted that reformulation was very expensive, required a long time to accomplish, and would under certain circumstances require the use of more expensive inputs. Some of these comments, from the shortening or baked products industries, gave examples

of recently developed commercial shortenings that were lower in *trans* fat than currently used shortenings. Several comments stated that, although alternative shortenings exist, they may not be a practical solution for reformulation because of expense or limited supply of the alternative shortenings and because time and expense for product development for reformulation would still be needed. Other comments stated that the private benefits of reformulation would not exceed private costs unless the declaration of *trans* fat on the food label was on a separate line on the Nutrition Facts panel or was in some way more prominent than in the November 1999 proposal. Some comments emphasized the disadvantages of reformulation for the cookies and crackers category, stating that FDA's estimate of 15 percent reduction in *trans* fat from those products was an overestimate.

In response to the comments about difficulties of reformulation, FDA notes that the analysis for the November 1999 proposal did include the cost of reformulation and the time needed for reformulation, but did not include higher ingredient costs for reformulation. In the long run, ingredient costs may not actually increase, because of increased industrial capacity to produce ingredients made with new technologies. In response to the comments about the cookies and crackers category, FDA acknowledges that its own projection of much higher reformulation for this category than for other baked products may have been unrealistic. Also in response to the comments, FDA notes that the emergence of commercial shortenings with lower *trans* fat content indicates that the reformulation of some baked products is feasible. Moreover, within these baked product categories there is a significant variation in *trans* fat content. Therefore, products with significantly higher than average amounts of *trans* fat compared with competing products will face competitive pressures

to reduce the amount of *trans* fat in their products. In response to the comment about prominence of *trans* fat on the nutrition label, FDA notes that, in this final rule, the declaration of *trans* fat is prominent and straightforward, on a separate line below *trans* fat.

After consideration of the comments and our own re-evaluation, we continue to believe that, ultimately, some proportion of baked products will be reformulated in most subcategories: Crackers, cookies, biscuits, tortillas, quick breads and muffins, doughnuts and sweet rolls, cakes, pies, pancakes and waffles. (In the categories of yeast breads and rolls, it is unlikely that reformulation will occur because yeast breads are relatively low in fat and typically contain less than 0.5 g *trans* fat per labeled serving.) However, there were disparate views among the comments regarding the availability of reformulated shortenings and the technical difficulty of baked product reformulation. Therefore, because of this uncertainty, we have opted for a more conservative approach and are not including a quantitative estimate of reformulation of baked goods in the analysis of the benefits and cost of *trans* fat labeling. We chose not to include a quantitative estimate of reformulation of baked goods so as not to overestimate the benefits of this rule. To the extent that reformulation of baked goods does occur, this analysis will underestimate the benefits of *trans* fat labeling.

Because of the existence of commercial shortenings with lower *trans* fat content, as pointed out in comments, FDA evaluated whether *trans* fat labeling might also result in reformulation of household shortenings to be lower in *trans* fat. Current household shortenings are lower in *trans* fat than current commercial shortenings, with some household products having only about half as much *trans* fat as some commercial products. This fact suggests that the

potential for lowering the *trans* fat content of household shortening is not as great as the potential for lowering the *trans* fat in current commercial shortenings. However, some household shortenings are currently making comparative saturated fat claims related to butter, and household shortenings may experience competitive pressure from some reformulated stick margarines due to *trans* fat labeling. Because of the uncertainty, FDA chose not to include a quantitative estimate of reformulation of household shortening so as not to overestimate benefits of this rule. To the extent that reformulation of household shortening does occur, this analysis will underestimate the benefits of *trans* fat labeling.

(Comment 37) Some comments discussed reformulation of other products, including potato chips, corn chips and similar snacks, microwave popcorn, and candy. Several of these comments emphasized the difficulty of reformulating products in these categories because of the expense, the time required, and the need for costly ingredients. Some of the comments suggested that, because of the difficulties of reformulation, *trans* fat labeling would put these categories of products at a competitive disadvantage. Other comments suggested that FDA's projected decrease in *trans* fat intake was an overestimate because *trans* fat labeling would not apply to a major source of *trans* fat: foods eaten at restaurants, especially French fried potatoes.

FDA did not project quantitative decreases in *trans* fat intake due to reformulation of other products, such as chips, microwave popcorn and candy, because these products contribute a smaller proportion of *trans* fat intake and because FDA did not have enough information to make quantitative reformulation estimates for these product categories. FDA is aware of the development of stable frying oils low in *trans* fat and suitable for chips, and

notes that there is interest in development of fats and oils lower in *trans* fat for many product categories (Refs. 120 to 122 and 151). At least one manufacturer has announced the reformulation of its snacks and chips to decrease *trans* fat (Ref. 150). To the extent that these product categories reformulate to decrease *trans* fat, the decrease in *trans* fat intake projected in this analysis will be an underestimate.

FDA acknowledges that a large proportion of the U.S. French fried potato intake is consumed in restaurants. Foods typically consumed in restaurants also include other food sources of *trans* fat. Restaurant food is not subject to mandatory nutrition labeling requirements, unless a nutrition-related claim is made. In its estimate of reformulation, FDA did not project reformulation of French fries or of baked goods. Therefore, FDA's estimate did not assume reformulation of restaurant foods. However, FDA is aware of some interest by restaurants in using absence of *trans* fat as a marketing device to gain competitive advantage (Ref. 123). If, as seems possible, frying oils and shortenings are developed for reformulation of packaged foods and become available in the market, they may become competitive choices with traditional fats and oils, even for restaurants that do not wish to use absence of *trans* fat for competitive advantage. To the extent that restaurants adopt reformulated baking and frying oils and purchase other products reformulated to be lower in *trans* fat, the decrease in *trans* fat intake projected in this analysis will be an underestimate.

iii. *Quantitative decrease in intake.* Table 2 of this document summarizes FDA's revised estimate of projected decreases in *trans* fat intake due to labeling. In table 2, current *trans* fat intake from margarine is 0.359 percent of energy, reduced 15 percent from the 0.423 percent of energy intake in table

1 of this document to adjust for the estimated 15 percent of margarine that has already been reformulated to remove *trans* fat. This adjustment reduces the total *trans* fat intake from hydrogenated products to 1.96 percent of energy in table 2, compared with 2.03 percent of energy in table 1. Table 2 shows that, by the effective date of the rule, FDA projects that *trans* fat intake will decrease by 0.0378 percent of energy. This decrease will be composed of 0.0359 percent of energy due to removal of 10 percent of *trans* fat from margarine by reformulation, and an additional 0.0019 percent of energy due to direct consumer choice.

TABLE 2.—ESTIMATED DECREASES IN *Trans* FAT INTAKE AND CONTRIBUTION FROM FOOD GROUPS DUE TO LABELING, AT EFFECTIVE DATE OF RULE

	Before Effective Date of Rule	Change at Effective Date of Rule	
	Mean daily *trans* intake[1]	Decrease in *trans* fat contribution from food group	Decrease in *trans* fat intake
Food group	Percent of energy from *trans* fat	Percent decrease in *trans* fat	Decrease in percent of energy from *trans* fat
Total Margarine	0.359%[2]	10%	0.0359%[3]
Other food groups with partially hydrogenated fats and oils	1.605%	none	
Total from hydrogenated products	1.964%		
Total decrease due to reformulation			0.0359%
Additional decrease due to consumer choice			0.0019%
Total decrease			0.0378%

[1] *Trans* fat intake for men and women age 20 and over from CSFII 1994–96, see table 1 of this document.
[2] *Trans* fat intake from margarine, 0.359 percent of energy, already decreased by 15 percent from intake in table 1, to account for margarine that has already been reformulated to decrease *trans* fat.
[3] Estimated decrease due to consumer choice at effective date is 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation.

iv. *Substitutions for trans fat.* In the November 1999 proposal, FDA assumed that manufacturers would most likely replace *trans* fat in margarine with: (1) *Cis*-monounsaturated fat, (2) 50 percent *cis*-monounsaturated fat and 50 percent *cis*-polyunsaturated fat, or (3) 50 percent *cis*-monounsaturated fat and 50 percent saturated fat, and that they would most likely replace *trans* fat in baked products with 50 percent *cis*-monounsaturated fat and 50 percent saturated fat (64 FR 62746 at 62771). In making these assumptions, FDA relied, in part, on a report from RTI estimating that current food technology would

require the incorporation of about 0.5 g saturated fat for every 1 g *trans* fat removed by reformulation (64 FR 62746 at 62767).

(Comment 38) Some comments stated that FDA had ignored the question of macronutrient substitutions, or had assumed that reformulation would replace *trans* fat with 100 percent *cis*-monounsaturated fat. According to the comments, functional requirements for margarines, shortenings and baked products would require that some *trans* fat be replaced by saturated fat, and this requirement was not accounted for in FDA's projections for reformulation. Other comments noted FDA's assumptions regarding macronutrient substitutions, but stated that FDA had overestimated the extent to which *trans* fat could be replaced by *cis*-unsaturated fat, because of functional and cost requirements of various products. These comments generally implied that FDA had overestimated the expected amount of reformulation because saturated fat would need to replace *trans* fat in any reformulation. Comments pointed out that the amount of saturated fat, a cholesterol-raising fat, is already declared on the nutrition label. Therefore, according to the comments, replacement of *trans* fat with saturated fat would not provide a competitive advantage or an incentive to reformulate and, with higher total saturated fat, the reformulated product might not meet the criteria for proposed defined nutrient content claims.

In response to the comments, FDA notes that it did consider the type of macronutrients substituted for *trans* fat, and these were accounted for in the mathematical model used to calculate the health benefits (64 FR 62746 at 62771). FDA is aware that there is a range of functional requirements for margarines and spreads, including tub and stick forms and regular and lower fat varieties. Therefore, FDA assumed a range of ingredient substitutions for

margarines and spreads, including both saturated and *cis*-unsaturated fat. Replacement of *trans* fat with a range of combinations of saturated and *cis*-unsaturated fat in margarines and spreads is consistent with reports from North America and Europe (Refs. 104, 124, 125, 126, 127, and 128). In a survey of U.S. margarines, tub margarines with *trans* fat less than 0.5 g per serving did not have increased saturated fat compared with other tub margarines (Ref. 104). In the U.S. study, a stick margarine with less than 0.5 g *trans* fat per serving had higher saturated fat than other stick margarines with comparable fat content, but had lower saturated fat plus *trans* fat than the other stick margarines (Ref. 104). FDA is aware that the functional requirements for baked products and shortenings may not allow the wide range of substitutions possible in margarines and spreads. Rather, the functional requirements for baked products will likely require replacement of at least some of the *trans* fat with saturated fat. This partial replacement of *trans* with saturated fat is consistent with reports by industry observers (Refs. 121 and 122) and with the examples of the alternative commercial shortenings described in several of the comments. In these examples, the shortenings reformulated to be lower in *trans* fat were higher in saturated fat but were lower in total saturated fat plus *trans* fat than were the traditional, nonreformulated shortenings. Under this final rule, products lower in both saturated fat and *trans* fat will have a competitive advantage because the rule requires prominent declaration of both types of fat on the label.

Based on its consideration of the comments and its own evaluation, FDA continues to believe that the likely substitutions for *trans* fat for margarines will be as described in the November 1999 proposal (64 FR 62746 at 62771). FDA does not have enough information to project the substitutions for *trans*

fat due to direct consumer choice, and therefore assumes (for simplicity) that direct consumer choice will show the same range of substitutions as does margarine reformulation. We will describe the effects of these substitutions for *trans* fat on the health benefits of *trans* fat labeling in section VI.E of this document.

Because of the functional requirements for baked products, FDA continues to believe that the most plausible replacement for *trans* fat in baked products is 50 percent *cis*-monounsaturated fat and 50 percent saturated fat. However, because of the uncertainty in quantitative estimation of baked product reformulation, FDA is not including baked product reformulation in its quantitative estimate of benefits and costs of *trans* fat labeling. As note earlier, to the extent that baked products are reformulated, this analysis will be an underestimate of the actual benefits of this rule.

D. Costs

The costs of this rule are the activities that change as a result of this rule. The total cost of these regulations is the sum of the total testing costs, total relabeling costs, and total reformulation costs. All labels must be in compliance with this final rule by a single effective date. All costs are estimated at the effective date, presumed to be 30 months from the publication date of this final rule. If the effective date is more than 30 months from the date of publication, then the actual costs of this rule will be lower than estimated here.

1. Products Affected

This final rule covers all food and dietary supplement labeling within FDA's jurisdiction. With a few exceptions, labeling for all FDA regulated foods and dietary supplements will have to be changed by the next uniform effective date following publication of this rule, or about 2 to 3 years after the date

of publication. One exception is for products with less than 0.5 g *trans* fat per serving that also use the "simplified format" for labeling and that do not make nutrition claims or declare vitamins or minerals. The labeling for these products will not have to be changed. FDA does not have data to estimate how many products fall into this category, so the cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule. The other exception is for products that sell less than 100,000 units per year in the United States, that are made by firms that have fewer than 100 employees, that do not make nutrition or health claims, and that have filed a notification with FDA in accordance with § 101.9(j)(18). These products are not required to display the Nutrition Facts panel that is being amended by this rule. Again, FDA does not have data to estimate how many products fall into this category, so the cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule.

To estimate the costs of this rule, FDA has used the FDA Labeling Cost Model developed for FDA under contract by RTI International in April 2002 (Ref. 129). This labeling model has more current data than the previous labeling cost model developed for the implementing rules of the 1990 amendments (Ref. 74). The model indicates that there are approximately 300,000 food and dietary supplement stock keeping units (SKUs) sold in the United States in categories for which some products will need to be relabeled. A SKU is a specific product sold in a specific size. For example, there is one SKU for 16 ounce (oz) containers of Brand X Diet Peach Tea. The same brand and flavor of tea (a product) in a 12 oz container would be another SKU, and a 12 oz container of the same brand but different flavor of tea would be still another SKU. Based on information from the food industry, the model assumes

that, on average, there are 5 SKUs per product, yielding a total of about 60,000 products potentially affected by this rule. Table 3 of this document shows the data on the number of SKUs and products affected. From the categories listed in table 3 as "Selected Beverages," "Selected Candy," "Selected Condiments, Dips and Spreads," and "Selected Dressings and Sauces," FDA excluded products, such as bottled water, gum, jam, and vinegar, that qualify for the "simplified" format and are certain not to be affected by this rule. Even with these products removed this estimate is still certain to be an overestimate of the actual SKUs and products affected by this rule because FDA has imputed costs to all products and SKUs within these broad product categories. Labels on many products categories such as "Selected Beverages" and "Dietary Supplements" are not likely to need to be changed. However, FDA has no basis to make better estimates of the actual number of products and SKUs affected by this rule.

TABLE 3.—NUMBER OF SKUS AND PRODUCTS AFFECTED BY PRODUCT CATEGORY

Product Categories	Number of SKUs	Number of Products
Baked Goods	47,200	9,400
Baking Ingredients	7,900	1,600
Baby Foods	700	100
Selected Beverages	31,500	6,300
Breakfast Foods	3,600	700
Selected Candy	13,500	2,700
Selected Condiments, Dips and Spreads	15,200	3,000
Dairy Foods	33,800	6,800
Desserts	10,700	2,100
Dietary Supplements	29,500	5,900
Selected Dressings and Sauces	14,200	2,800
Eggs	5,800	1,200
Entrees	10,300	2,100
Fats and Oils	3,100	600
Fruits and Vegetables	25,100	5,000
Seafood	6,800	1,400
Side Dishes and Starches	18,000	3,600
Snack Foods	17,800	3,600

TABLE 3.—NUMBER OF SKUS AND PRODUCTS AFFECTED BY PRODUCT CATEGORY—Continued

Product Categories	Number of SKUs	Number of Products
Soups	3,700	700
Weight Control Foods	1,300	300
Total	299,700	59,900

2. Testing Costs

In the proposed analysis, FDA assumed that all product formulations that include partially hydrogenated oil as an ingredient would be tested to determine the quantity of *trans* fat (except for margarine products, which were all expected to reformulate). Some comments stated that FDA's estimate of the number of products that would need to be tested was too low because products in other categories than those acknowledged by FDA could potentially contain a reportable amount of *trans* fat. Indeed, other comments stated that all products would have to be tested for *trans* content. FDA disagrees with the comment that all products need to be tested because manufacturers will know that some products do not contain *trans* fat, but does agree that more products need to be tested than previously estimated. In the proposed analysis, FDA estimated costs for testing only for the estimated portion of products containing partially hydrogenated oil in several categories of foods anticipated to be most affected by the rule (an estimated 42,000 products). In this final analysis based on information in the FDA Labeling Cost Model (Ref. 129), FDA estimates that 60,000 food products in categories that could possibly include *trans* fat will be tested for *trans* fat content as a result of this rulemaking.

In the proposed rule, FDA used a per product cost of testing for *trans* fat of $200. Some comments stated that this estimate is too low. They stated that tests had to be calibrated for each type of food to demonstrate accuracy of the test in the food matrix. FDA notes that manufacturers of many different types

of foods have already had their products tested, so that much of the calibration has already been done. The new Labeling Cost Model includes data on the cost of testing for *trans* fat. Included in the analytical testing estimate is the cost of testing two samples of the product, one hour of labor to prepare and package the product (at $14.73 per hour) and delivery charges for one two-pound package delivered overnight (at $26.30). The model reports a range of testing costs for *trans* fat given in table 4.

TABLE 4. RANGE OF PER PRODUCT AND TOTAL TESTING COSTS

	Low	Medium	High
Cost per Product	$261	$291	$371
Total Testing Cost	$15,660,000	$17,460,000	$22,260,000

One comment suggested that butter and other products with high butter fat contents, such as some ice cream, would contain a reportable amount of naturally occurring *trans* fat, and that therefore, FDA had underestimated the costs of testing these products. In this final analysis, FDA has included testing and relabeling costs for all dairy products including butter and other products that are high in butter fat.

3. Relabeling Costs

In the analysis of the proposed rule, FDA estimated that 39,000 SKUs were associated with the 32,000 products that would change their information panels at a cost of $30 million. During the comment period reopened November 2002, FDA received comments that we would have to reestimate the relabeling costs for the final rule. Under this final rule many more labels will have to be changed than under the proposed rule. FDA has used the new Labeling Cost Model to reestimate the relabeling costs of this final rule. FDA estimates that almost 300,000 SKUs will be changed. Included in the cost of relabeling are administrative, graphic design, pre-press preparation, printing

and engraving, and the lost value of discarded labels. Across product categories, the average low relabeling cost per SKU is about $250 and the average high relabeling cost per SKU is $585. The reported estimated costs of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 5 shows the total estimated costs of relabeling per product category and for the entire industry.

TABLE 5. RANGE OF RELABELING COSTS BY PRODUCT CATEGORY

Product Categories	Low	Medium	High
Baked Goods	$7,890,000	$12,313,000	$21,674,000
Baking Ingredients	$1,105,000	$1,745,000	$2,968,000
Baby Foods	$70,000	$107,000	$175,000
Selected Beverages	$21,682,000	$28,026,000	$38,276,000
Breakfast Foods	$578,000	$954,000	$1,636,000
Selected Candy	$1,664,000	$2,623,000	$4,330,000
Selected Condiments, Dips and Spreads	$4,710,000	$6,709,000	$9,836,000
Dairy Foods	$8,359,000	$12,953,000	$20,604,000
Desserts	$2,197,000	$3,558,000	$6,040,000
Dietary Supplements	$12,744,000	$19,017,000	$31,712,000
Selected Dressings and Sauces	$2,532,000	$3,835,000	$5,805,000
Eggs	$1,762,000	$2,634,000	$4,722,000
Entrees	$1,651,000	$2,592,000	$4,198,000
Fats and Oils	$886,000	$1,397,000	$2,138,000
Fruits and Vegetables	$10,738,000	$15,154,000	$23,010,000
Seafood	$1,598,000	$2,304,000	$3,351,000
Side Dishes and Starches	$2,460,000	$3,969,000	$6,718,000
Snack Foods	$2,694,000	$4,092,000	$6,604,000
Soups	$1,073,000	$1,514,000	$2,221,000
Weight Control Foods	$149,000	$224,000	$382,000
Total	$86,542,000	$125,720,000	$196,400,000

4. Margarine Reformulation Costs

One consequence of this regulation will be the reformulation of some foods to reduce levels of *trans* fat. Because those changes in food composition are attributable to this rule, the costs of reformulation are counted here. The benefits to consumers of being able to choose reformulated foods containing

less *trans* fat will be counted in section VI.E of this document. In the analysis of the proposed rule, FDA estimated the average reformulation would cost $440,000 per product and would take a full year. Some comments stated that reformulation was very expensive, required a long time to accomplish and would, under certain circumstances, require the use of more expensive inputs. No comments contradicted FDA's estimate of the per product cost of reformulation or provided information to change that estimate, so FDA will continue to use a per product reformulation cost of $440,000. In the proposed analysis FDA assumed that only large firms would reformulate. There was no controversy over this assumption.

As mentioned previously, based on comments, FDA estimates that 15 percent of margarine products have already been reformulated to eliminate *trans* fat. For margarine reformulation, FDA has estimated no increase in ingredient costs, because the price of reformulated margarine products that are already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs.

Therefore, FDA estimates that 10 percent of the margarine products that have not yet been reformulated will be reformulated to reduce *trans* fat content to less than 0.5 g per serving. We assume that the products that will be reformulated contain average amounts of *trans* fat, so the fraction of margarine products reformulated will equal the fraction of *trans* fat removed from margarine. The reformulation will therefore reduce the *trans* fat content of margarines as a whole by 10 percent. In the analysis for the proposed rule,

FDA estimated that there were 820 margarine products. Data in the new Labeling Cost Model indicate only 84 margarine products. Both estimates will be used to derive a range for the number of margarine products that will reformulate as the result of this rule from 8 (10 percent of 84) to 82 (10 percent of 820), if 10 percent of the total number of margarine products are reformulated. Table 6 shows the cost of margarine reformulation.

TABLE 6.—RANGE OF MARGARINE REFORMULATION AND TOTAL COST

	Low	Medium	High
Products Reformulating	8	45	82
Total Cost	$3,520,000	$19,800,000	$36,080,000

FDA has not attempted to estimate the ongoing increased cost of substitutes for partially hydrogenated oil. Competition provides producers with incentives to use the least expensive ingredients that are acceptable for the quality of product they are making. Therefore, in general, any change in existing formulations (such as is expected to occur as a result of this rule) can increase the cost of ingredients. Even a very small increase in the price of a minor ingredient can amount to an increase in production costs of millions of dollars when multiplied by millions of units. However, there is good reason to believe that in the long run ingredient costs may not increase. To the extent that producers rely on newly formulated ingredients made with new technologies, the price of these ingredients largely depends on the industrial capacity to produce them. As the demand for such ingredients increases, producers will have more incentive to increase capacity and the prices of these ingredients will fall. In the case where producers make use of different mixes of oils, agricultural inputs are well known for being able to be supplied in greater and greater quantities without an increase in price. FDA does not have sufficient information on the types of substitutes that will be used, on the

volume of substitutes that will be needed, or on the future price of the substitutes at the time that reformulation is completed.

5. Cost Summary

Costs for testing, relabeling, and reformulation are all expected to occur by the first effective date of the final rule, or about 2 to 3 years after publication. Table 7 shows the estimates of total cost.

TABLE 7.—RANGE OF COSTS BY CATEGORY AND TOTAL COST

Cost Category	Low	Medium	High
Testing	$15,660,000	$17,460,000	$22,260,000
Relabeling	$86,542,000	$125,720,000	$196,400,000
Reformulation	$3,520,000	$19,800,000	$36,080,000
Total	$106,000,000	$163,000,000	$255,000,000

FDA acknowledges that there is a significant degree of uncertainty in the cost estimates provided here. The most significant source of potential divergence from the reported estimates would be an ongoing increased cost of substitutes for partially hydrogenated oil for producers of reformulated products. FDA has not included any costs for this item in this analysis, so that, if substitute oils do cost more, the costs here are underestimates.

Reformulation is a second significant area of uncertainty. The unknowns include the number of products that will be reformulated, the cost of reformulation, the number of abandoned attempts at reformulation, the length of time actually needed to reformulate products, and the degree to which the reformulation of some products reduces the cost of reformulating other products of the same or different type. The estimates that are provided in this analysis might be either over- or underestimates of the actual costs of reformulation.

A third major area of uncertainty includes the number of labels that will be changed. Actual costs are likely to be lower than those estimated here

because this analysis estimated costs based on broad categories of products some of which will not have to change their labels.

E. Benefits

To estimate the health benefits of *trans* fat labeling in the November 1999 proposal, FDA followed the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA estimated: (1) The changes in *trans* fat intake that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided and dollar value of such benefits.

1. Changes in *Trans* Fat Intake

FDA has estimated the current *trans* fat intake of the population and the estimated changes in *trans* fat intake. Based on comments received and on its own reevaluation, FDA revised its estimate of current *trans* fat intake, shown in table 1 (section IX.C) and its projected estimate for changes in *trans* fat intake due to labeling (table 2, section IX.C). The estimate projects quantitative decreases in *trans* fat intake with implementation of the final rule, and discusses the qualitative replacement of *trans* fat by other types of fat.

2. Changes in Health States

In the November 1999 proposal, FDA used two methods to estimate the potential decrease in CHD likely to result from decreased intake of *trans* fat in response to the labeling change.

a. *Method 1.* Decrease in CHD risk due to decreased serum concentrations of LDL–C.

b. *Method 2.* Decrease in CHD risk due to decreased serum concentrations of LDL–C and increased serum concentrations of HDL–C. FDA also reviewed the association of CHD risk with *trans* fat intake found in large prospective observational cohort studies.

As described in section IV of this document, in the November 1999 proposal FDA concluded that the effects of *trans* fatty acids on serum LDL–C should be the primary criterion for whether *trans* fatty acids influence CHD risk. In Method 1, FDA used changes in the primary criterion, serum LDL–C, to evaluate the effects of *trans* fat intake on CHD risk (64 FR 62746 at 62768). Additionally, as described in section IV of this document, although FDA did not place primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL–C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored. Therefore, the economic analysis used changes in both HDL–C and LDL–C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL–C (64 FR 62746 at 62769).

Section IV of this document notes that observational epidemiological studies can provide evidence of an association between a risk factor and a disease, but cannot establish direct cause and effect. Therefore, FDA considered the evidence from observational epidemiological studies, including large prospective (cohort) studies, as indirect evidence for a relationship between *trans* fat intake and CHD risk. In the November 1999 proposal, FDA found that the prospective studies of *trans* fat intake and CHD risk consistently reported a greater risk of CHD attributable to *trans* fat intake than would be

accounted for by either Method 1 (changes in LDL–C) or by Method 2 (changes in both LDL–C and HDL–C) (64 FR 62746 at 62770 to 62771). The estimates in Method 1 and Method 2 are calculated using factors from regression equations summarizing the results of short-term feeding trials (intervention studies). In the intervention studies, *trans* fat is fed to people for a few weeks, changes in serum lipids are measured, and it is assumed that the CHD risk associated with *trans* fat intake occurs through the mechanism of changes in LDL–C and possibly HDL–C. In contrast, the prospective studies measure actual CHD occurrence in a large group of people over a period of years, and describe all CHD risk associated with *trans* fat intake, regardless of the mechanism of action by which *trans* fat intake may be associated with CHD. Thus, the results of the prospective studies suggest that there may be additional mechanisms by which *trans* fat contributes to CHD risk. Because prospective studies do not show direct cause and effect, and because the relative risks determined in observational studies are imprecise, FDA did not use the results of the prospective studies in quantitative estimates of changes in *trans* fat intake and CHD risk. However, FDA noted that, if there are additional mechanisms by which *trans* fat contributes to CHD risk, as suggested by the prospective studies, then the actual benefits may be greater than estimated using either Method 1 (changes in LDL–C) or Method 2 (changes in LDL–C and HDL–C) (64 FR 62746 at 62771).

Sample calculations using Method 1 and Method 2 are summarized in Table 8 in this document. The table illustrates a decrease in *trans* fat intake of 0.1 percent of energy (calories) and shows the factors FDA used to relate a given decrease in *trans* fat intake to a corresponding change in CHD risk. The estimate shows that replacement of 0.1 percent of energy from *trans* fat

with the same percent of energy from *cis*-monounsaturated fat would decrease CHD risk by 0.147 percent based on changes in LDL–C (-0.1 x 1.5 x 0.7 x 1.4 = -0.147), and 0.287 percent based on changes in both LDL–C and HDL–C (-0.1 x -0.4 x -2.5 x 1.4 = -0.140 and -0.147 plus -0.140 = -0.287). FDA used these estimation methods to project the decrease in CHD risk in the November 1999 proposal (64 FR 62746 at 62767).

TABLE 8.—SAMPLE CALCULATION FOR CHANGE IN CHD RISK WITH SUBSTITUTION OF *Cis*-MONOUNSATURATED FAT FOR *Trans* FAT

Estimation Method	Change in *Trans* Intake (% of Energy)	Type of Serum Lipid	Factor for Change in Serum Lipids (mg/dL per 1% of Energy)	Factor for Change in CHD Risk (% per mg/dL)	Factor for Adjustment of Regression Dilution	Change in CHD Risk (%)
Method 1 LDL	-0.1	LDL	1 5	0.7	1.4	-0.147
Method 2 LDL + HDL	-0.1	LDL	1.5	0.7	1.4	-0.147
		HDL	-0.4	-2.5	1.4	-0.14
		LDL+HDL				-0.287

In the scientific literature, *cis*-monounsaturated fat is commonly used as a reference point in describing effects of *trans* fat intake. Therefore, FDA first estimated the effect on CHD risk by assuming that a given amount of *trans* fat would be replaced by the same amount of *cis*-monounsaturated fat in the diet (table 8 in this document and 64 FR 62746 at 62767). However, it is likely that *trans* fat in the diet would actually be replaced by a combination of *cis*-monounsaturated fat, *cis*-polyunsaturated fat, and saturated fat. Therefore, FDA also considered the changes in LDL–C and HDL–C associated with replacement of *trans* fat by different types of fatty acids or carbohydrate (64 FR 62746 at 62767 to 62770). Table 9 in this document summarizes the factors for changes in LDL–C and HDL–C with different macronutrients and combinations of macronutrients replacing *trans* fat. FDA accounted for the replacement of *trans* fat with different combinations of macronutrients by projecting a range of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits (64 FR 62746 at 62771–62773).

TABLE 9.—SUMMARY OF FACTORS FOR CHANGE IN SERUM LIPIDS WITH SUBSTITUTION OF *Trans* FATTY ACIDS FOR DIFFERENT TYPES OF FATTY ACIDS OR CARBOHYDRATE

TYPE OF FATTY ACID REPLACED BY 1 PERCENT OF ENERGY FROM *Trans* FAT

Type of serum lipid	*Cis*-monounsaturated	*Cis*-polyunsaturated	Saturated	Carbohydrate	Half *cis*-monounsaturated and half *cis*-polyunsaturated	Half *cis*-monounsaturated and half saturated	Half *cis*-monounsaturated and half carbohydrate
	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy
LDL	1.5	1.81	-0.02	1.26	1.66	0.74	1.38
HDL	-0.4	-0 34	-0.53	-0.06	-0 37	-0.47	-0.23

(Comment 39) As described previously in this document, FDA received numerous comments in support of the November 1999 proposal. Several of these comments noted specifically that labeling of *trans* fat has the potential for substantial public health benefits. A number of comments noted that consumption of *trans* fat increases the risk of CHD by increasing total blood cholesterol and LDL–C, and that *trans* fat labeling would enable consumers to decrease their *trans* fat intake and therefore decrease their risk of CHD. Some comments added that, because *trans* fat also increases the risk of CHD by decreasing HDL–C, therefore the health benefits of *trans* fat labeling would be greater than the benefits associated with the effect of *trans* fat on LDL–C alone. A few comments specifically stated that the prospective studies suggest that there may be other biological mechanisms by which *trans* fat contributes to CHD, in addition to the effects of *trans* fat on LDL–C and HDL–C. These comments therefore supported the possibility that the actual benefits of *trans* fat labeling may be greater than FDA's estimate using either Method 1 (LDL–C) or Method 2 (LDL–C and HDL–C).

Other comments, which were opposed to the November 1999 proposal or some of its provisions, questioned FDA's conclusions regarding the net health benefits of *trans* fat labeling. Some comments stated that the potential harm to the public remedied by *trans* fat labeling was not sufficient to outweigh the cost burden to specific industries. These comments suggested that,

although *trans* fat was shown to increase LDL–C in some studies, the evidence was inconclusive on how to quantitate the increase in LDL–C and CHD risk due to *trans* fat intake and on whether the increase in LDL–C and CHD risk due to *trans* fat intake were as large as those due to saturated fat. These comments suggested that FDA's estimate of health benefits of *trans* fat labeling was too high. One comment stated that it is premature to conclude that *trans* fat intake lowers HDL–C because many intervention studies showed that *trans* fat intake causes only a small decrease or has no effect on HDL–C. The comment implied that consumption of *trans* fat may not increase CHD risk by decreasing HDL–C. A few comments cited an FDA statement from the November 1999 proposal that no dose-response relationship had been demonstrated between *trans* fat intake and CHD (64 FR 62746 at 62752). The comments argued that, therefore, it is not possible to project quantitative health benefits due to *trans* fat labeling. One comment also stated that the health benefits estimate was inaccurate because it did not account for either other CHD risk factors, such as obesity, or other CHD prevention efforts.

A few comments questioned whether health benefits could result from *trans* fat labeling because the in the intervention studies the intakes of *trans* fat were very high and not representative of U.S. intakes of about 5.3 g/d (3 percent of calories). Some comments stated that, even if *trans* fat has adverse health effects at higher levels of intake, there is no clinical evidence that lower levels of intake, such as 0.5 g *trans* fat in a serving of a food product, has any adverse effect. These comments therefore questioned whether health benefits could result from labeling of *trans* fat present in relatively small amounts in individual foods. Other comments suggested that the emphasis on *trans* fat in the proposed labeling regulations was out of proportion to the

emphasis on saturated fat, because the overall amount of saturated fat in the diet is approximately five times that of *trans* fat. The comments stated that, therefore, decreased *trans* fat intake has much less potential for lowering CHD risk than does decreased saturated fat intake, and this should be considered when estimating the health benefits of *trans* fat labeling.

Regarding the comments that questioned whether the increase in LDL–C and CHD risk due to *trans* fat intake could be quantitated and whether the increase in LDL–C and CHD risk due to *trans* fat intake were as large as those due to saturated fat, FDA stated in the review of the science in the 1999 proposal (64 FR 62746 at 62753) that the available studies did not provide a definitive answer about whether *trans* fat has an effect on LDL–C and CHD risk equivalent to saturated fat on a gram-for-gram basis. FDA noted that interpretation of the intervention studies is complicated because, in the individual studies, *trans* fatty acids replace other dietary fatty acids that also affect serum cholesterol levels (64 FR 62746 at 62751). This evaluation was based on a review and analysis of the individual studies, it was not done for purposes of an economic analysis. To overcome the difficulties in interpreting individual intervention studies, in the November 1999 proposal FDA used regression equations based on a meta-analysis of intervention trials to quantitatively estimate the relationship between *trans* fat and LDL (Refs. 62, 65, and 69) in its calculation of the health benefits of *trans* fat labeling (64 FR 62746 at 62768–62770). As noted in section IV of this document, and in the November 1999 proposal, the regression equations do predict a very similar increase in LDL–C with each one percent of energy increase in either saturated fat or *trans* fat. Thus, table 9 in this document shows that the change in LDL–C is negligible when one percent of energy from *trans* fat is substituted for

saturated fat. Therefore, FDA disagrees with the comments that stated that the increases in LDL–C and CHD risk due to *trans* fat intake could not be quantified and were not as large as those due to saturated fat and that FDA's estimate of these health benefits of *trans* fat labeling was too high.

Regarding the comment suggesting that it is premature to conclude that *trans* fat intake lowers HDL–C, section IV of this document states that Federal Government advisory groups (Refs. 88 to 90, 140) and an advisory group of health professionals (Ref. 91) have stated that substitution of *trans* fat for saturated fat lowers HDL–C. Specifically, the Dietary Guidelines 2000 Advisory Report states that *trans* fatty acids tend to lower a protective form of serum cholesterol (HDL cholesterol) (Ref. 88). NCEP 2001 states that randomized clinical trials show that when *trans* fatty acids are substituted for saturated fatty acids, HDL cholesterol levels are lower, with a dose response effect observed (Ref. 89). The IOM/NAS states that the preponderance of the data suggest that hydrogenated fat/*trans* fatty acids, relative to saturated fatty acids, result in lower HDL cholesterol concentrations (Ref. 90). AHA 2000 states that it has been established that dietary *trans*-unsaturated fatty acids can increase LDL cholesterol and reduce HDL cholesterol (AHA 2000, p. 2300) (Ref. 91). Therefore, FDA disagrees with the comment that it is premature to conclude that *trans* fat intake may lower HDL–C. As described in Section IV of this document, although FDA did not place primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL–C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored. Therefore, we used changes in both HDL–C and LDL–C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted

qualification that the primary basis for the rule was the effect of *trans* fat on LDL–C (64 FR 62746 at 62769).

Regarding the comments discussing FDA's statement in the November 1999 proposal (64 FR 62746 at 62752) that no dose response relationship had been demonstrated between *trans* fat intake and CHD, this statement referred to the effect of *trans* fat on CHD risk in the observational studies, not to the effect of *trans* fat on LDL–C which was used to estimate the health benefits in Method 1 (LDL–C) and Method 2 (LDL–C and HDL–C). FDA's statement was a generalization regarding the observational studies overall, including both case control studies and prospective observational studies. However, the four large prospective studies did all show dose-response relationships between *trans* fat intake and CHD risk, but in two of the studies the dose-response relationship was not statistically significant in all analyses. In the Nurses Health Study, the dose response relationship at both 8 years and 14 years of followup was highly statistically significant (Refs. 21 and 38). In a Finnish study, the dose response relationship of *trans* fat with risk of CHD death was significant ($p = 0.004$), but was not significant for risk of major coronary event ($p = 0.158$) (Ref. 20). In a study of U.S. men, the dose response relationship was significant after statistical adjustment for major CHD risk factors ($p = 0.01$) but was not significant after additional adjustment for dietary fiber ($p = 0.2$) (Ref. 19). Therefore, the prospective studies were consistent with a dose-response relationship, although the relationship was not statistically significant in all analyses. Moreover, as discussed previously in this section, FDA's quantitative estimate of health benefits was not based on the prospective studies, but was based on the regression equations summarizing the results of the intervention feeding studies (tables 8 and 9 in this document and 64

FR 62746 at 62757–62770). The regression equations summarizing the effect of *trans* fat on LDL–C and HDL–C in the intervention studies did show a dose response relationship, as discussed in the November 1999 proposal and noted in section IV of this document. Additionally, the regression equations used by FDA in this document and in the November 1999 proposal were for purposes of making a quantitative estimate of the health benefits as part of an economic analysis and are consistent with newer regression equations in a study published in 2001 (Ref. 130). Therefore, FDA does not agree with the comment that it is not possible to calculate health benefits because there is no dose-response relationship for the adverse effects of *trans* fat.

FDA disagrees with the comment that the health benefits estimate did not account for other CHD risk factors. In the health benefits estimate, FDA used the factors shown in table 8 to calculate the amount of CHD risk associated with the expected amount of change in LDL–C and HDL–C. These factors were derived from large population studies of serum lipids and CHD risk, in which statistical methods accounted for other positive and negative risk factors for CHD.

Regarding the comment about the level of *trans* fat intake in the intervention studies, Section IV of this document explains that, because of uncertainty in intake estimates, caution must be exercised to avoid over-interpretation of the available dietary intake estimates and their relationship to the *trans* fat levels used in the intervention trials. However, in response to the comment, FDA notes some specific examples of intervention studies with lower *trans* fat intake. One example is the study of Judd et al., 1998 (Ref. 34), which found a significant increase in LDL–C with a difference in *trans* fat intake of 1.5 percent of calories between the *trans* fat test diet (3.9 percent

of calories from *trans* fat) and the comparison diet (2.4 percent of calories from *trans* fat). Another example is the study of Lichtenstein and coworkers (Ref. 82) which studied six test diets and reported a positive coefficient, i.e., a linear trend, for the association of the change in LDL–C levels among diets with the change in *trans* fat intake (including *trans* fat changes of 0.4 percent and 2.8 percent of calories). Such a linear trend does suggest that *trans* fat intakes below 3 percent of calories may influence LDL–C levels, and thus, CHD risk. Therefore, significant increases in LDL were found in specific intervention studies with *trans* fat intake at or below the reported average intake for the U.S. population.

FDA disagrees with the comment that disclosure of 0.5 g *trans* fat or greater in a food product has no public health importance and that health benefits may not result from labeling of *trans* fat present in relatively small amount in individual foods. As described earlier in sections III and V of this document, FDA does not need to demonstrate adverse health effects of 0.5 g *trans* fat in a food product in order to justify requiring disclosure of 0.5 g *trans* fat on food labels. Rather, FDA determined that the consistent provision of *trans* fat information on foods consumed throughout the day is of public health importance and can assist consumers in maintaining healthy dietary practices. Further, FDA has determined that the absence of *trans* fat information on foods requiring mandatory labeling would be misleading. However, for the purposes of economic analysis, the health benefits of decreasing *trans* fat intake by 0.5 g can be estimated quantitatively. In a 2,000 calorie diet, 0.5 g *trans* fat corresponds to approximately 0.2 percent of energy. (This correspondence holds because 1 g of fat = 9 kcal, so (0.5 x 9 x 100)/2000 = 0.2 percent of energy). Using the factors in table 8, replacement of 0.2 percent of energy from

trans fat with *cis*-monounsaturated fat would decrease CHD risk by 0.29 percent based on LDL–C and 0.57 percent based on LDL–C and HDL–C. Because CHD is so common in the U.S. population, a relatively small decrease in risk corresponds to a large number of cases and deaths avoided and large dollar value of such benefits, as shown in the example in section IX.A of this document. Awareness of *trans* fat contributions from food products containing 0.5 g and above will assist individual consumers in maintaining healthy dietary practices, reducing the average 2.6 percent of energy from *trans* fat consumed throughout the day.

FDA agrees with the comments that average saturated fat intake in the United States is about 5 times greater than average *trans* fat intake. FDA stated in the November 1999 proposal that it did not want to distract consumers from years of dietary guidance messages about saturated fat (64 FR 62746 at 62755). But the potential health benefits from decreasing *trans* fat intake compared with decreasing saturated fat intake do not depend solely upon the average total amount of each in the diet. The potential health benefits also depend upon the feasibility of decreasing intake of saturated fat compared with *trans* fat. Average U.S. saturated fat intake in 1980 was about 13 percent of energy and decreased to 11 or 12 percent of energy by the mid-1990s (Ref. 113). Many additional heart attacks and deaths might be prevented if saturated fat intake could be decreased to the recommended 10 percent of energy. The targeted decrease in saturated fat intake of one or two percent of energy can be compared with the average *trans* fat intake of 2 percent of energy from partially hydrogenated fats and oils. Labeling of *trans* fat will create new potential for decreased *trans* fat intake by providing an incentive to food manufacturers to reduce the amount of *trans* fat in their products and by providing consumers

with information they need to include *trans* fat content in their food purchasing decisions.

(Comment 40) Among the comments that supported the potential public health benefits of *trans* fat labeling, many noted that benefits would result from provision of *trans* fat information on product labels so that consumers could incorporate this information into their purchasing decisions. Several comments also specifically noted the likelihood that *trans* fat labeling would result in reformulation of products to be lower in *trans* fat, and suggested that the public health benefits would be large because reducing *trans* fat intake as a result of reformulation requires little effort by consumers. However, some comments did not agree that *trans* fat labeling would be read or understood by consumers, or that the labeling would affect purchasing decisions. These comments suggested that the net health benefits of *trans* fat labeling would be much smaller than FDA's estimate. Other comments did not agree that products could be reformulated in a manner that would result in net health benefits. Some of these comments stated that *trans* fat is beneficial because foods with *trans* fat replace foods with higher amounts of saturated fat. Some comments stated that feasible reformulations that would lower *trans* fat would also increase saturated fat, thereby reducing or eliminating health benefits. Other comments emphasized that manufacturers need competitive incentives in order to incur the costs of reformulation, and did not agree that the Nutrition Facts panel and label claims in the November 1999 proposal provided sufficient incentives for reformulation.

In the November 1999 proposal, FDA based its estimate of health benefits on scenarios of projected decreases in *trans* fat intake due to labeling and reformulation. As summarized in section VI.C of this document, FDA received

specific comments regarding the likely decrease in *trans* fat intake due to expected consumer responses to *trans* fat labeling and due to the projected amount of product reformulation. Based on the comments received, on the provisions of this final rule and on its own reevaluation, FDA has revised its estimate of the expected decrease in *trans* fat intake due to labeling (table 2, section VI.C). Because of uncertainties regarding the magnitude of consumer response to *trans* fat labeling we have chosen a very low estimate of consumer response to the new label, a decrease of 0.1 percent of *trans* fat intake (section VI.C.). As described in section IV of this document, current dietary guidance does not consider *trans* fat to be beneficial, but recommends that intake of both *trans* fat and saturated fat should be limited. When products containing partially hydrogenated fats or oils are reformulated to lower the *trans* fat content, functionality may require the reformulated products to have more saturated fat than the original product. However, as shown in a number of examples included with comments, the total amount of saturated fat plus *trans* fat in the reformulated product is commonly lower than in the original product. Substitution of the reformulated product for the original product in the diet would have net health benefits using Method 1, LDL–C, and even higher health benefits using Method 2, LDL–C and HDL–C. FDA acknowledges that different products have different functionality requirements for fats and oils, and the constraints on reformulation alternatives are different for tub and stick margarines and spreads, household shortenings, frying fats for snacks and chips, and baking fats for cookies, crackers, cakes and other baked goods. FDA has summarized specific comments regarding reformulation alternatives in section IX.C of this document, has taken these into account in projecting the expected amount of margarine reformulation (table 2), and is accounting for

the replacement of *trans* fat with different combinations of macronutrients in its models for calculating changes in valuation of health states in section IX.E.3 of this document. Therefore, FDA does not agree with the comments that feasible reformulations would eliminate health benefits by increasing saturated fat. In section V of this document, FDA stressed the importance of providing information on *trans* fat on the nutrition label to assist consumers in choosing healthier diets. As described in section IX.E.3 of this document, in response to comments regarding reformulation, FDA recognizes that different features of this final rule may tend to either increase or decrease the incentives for reformulation. Therefore, because of this uncertainty, in this analysis FDA is using a deliberately low estimate, 10 percent, for the decrease in *trans* fat intake due to margarine reformulation. Also, FDA is not using a quantitative estimate for any decrease in *trans* fat intake due to reformulation of baked products or of other products containing hydrogenated fats and oils. To the extent that the decrease in *trans* fat intake due to reformulation is greater than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

(Comment 41) As summarized in section IV.9 of this document, one comment recommended that comparisons of the health effects of saturated fat and *trans* fat should be explicit and consistent throughout the final rule. The comment noted that in FDA's November 1999 proposal, the preliminary regulatory impact analysis estimated that the effects of *trans* fat and saturated fat on LDL–C were similar for a given percent of energy, but the review of the science did not make a gram-for-gram comparison of the effects of saturated and *trans* fat. The comment stated that if there is uncertainty about the comparative effects of saturated fat and *trans* fat on LDL–C, then this should

be reflected in FDA's estimate of health benefits. The comment also noted that, in the preliminary regulatory impact analysis, use of Method 2, LDL–C and HDL–C, would approximately double the expected health benefits of *trans* fat labeling, compared with Method 1, LDL–C. The comment suggested that if the adverse health effects of *trans* fat are approximately double those of saturated fat, this should be taken into account in the provisions for labeling and claims. This comment also suggested that FDA had misinterpreted the relative risk results of the prospective observational studies and questioned whether these studies actually indicated that the risk of CHD due to *trans* fat intake was much greater than would be expected due to LDL–C and HDL–C. According to the comment, relative risk estimates in prospective studies depend on the base risk used for comparisons. Individuals in some study groups, such as the Nurses Health Study, may have lower overall CHD risk than individuals in the general population because the participants are volunteers whose lifestyles may be healthier than average. A systematic difference between the study and general populations may result in inaccuracies when the relative risk from the study population is related to the absolute risk in the general population.

A few comments to the November 15, 2002, notice to reopen the *trans* fat comment period questioned the scientific validity of certain of the observations and conclusions in the IOM/NAS report. The comments stated that the IOM/NAS report relied upon a regression equation in an article by Ascherio et al. (Ref. 83), published in the NEJM, for its observation that *trans* fatty acids may have a more adverse effect on CHD risk than saturated fatty acids and for its conclusion that, similar to saturated fatty acids, there is a positive linear trend between *trans* fatty acid intake and LDL–C and risk of CHD. The comments stated that the Ascherio et al. article was a commentary

that was not peer-reviewed and should not be accorded the weight given by the IOM report. Additionally, comments suggested that additional research is needed to establish whether there is a positive linear trend between *trans* fat intake and LDL–C. The comments asserted that there may be an alternate explanation for the results described by Ascherio et al., and mentioned unpublished work done at the University of Cincinnati. The comments did not mention the existence of any other evidence for a linear trend between *trans* fat intake and LDL–C, and implied that, in the absence of the Ascherio article (Ref. 83), there would be no basis for the existence of such a linear trend.

As stated in section IV.9 of this document, regardless of whether FDA reviewed the effects of saturated fat and *trans* fat on LDL–C and CHD risk for the science section or the regulatory impact section, the basic conclusion about those effects is the same. That is, both *trans* fatty acids and saturated fatty acids raise LDL–C levels, a major risk factor for CHD risk. FDA did state in the review of the science in the 1999 proposal (64 FR 62746 at 62753) that the available studies did not provide a definitive answer about whether *trans* fat has an effect on LDL–C and CHD risk equivalent to saturated fat on a gram-for-gram basis. However, as stated previously in both this section and section IV of this document, to overcome the difficulties in interpreting individual intervention studies, in the November 1999 proposal FDA used regression equations based on a meta-analysis of intervention trials to quantitatively estimate the relationship between *trans* fat and LDL (Refs. 62, 65, and 69) in its calculation of the health benefits of *trans* fat labeling (64 FR 62746 at 62768–62770). The regression equations do predict a very similar increase in LDL–C with each one percent of energy increase in either saturated fat or *trans* fat. The regression equations used by FDA in this document and in the

November 1999 proposal are appropriate for purposes of making a quantitative estimate of the health benefits as part of an economic analysis and are consistent with newer regression equations in a study published in 2001 (Ref. 130).

As previously described in this section and in section IV of this document, although FDA did not place primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL–C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored. Therefore, we used changes in both HDL–C and LDL–C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL–C (64 FR 62746 at 62769). As discussed in section V of this document, because of chemical and physiologic distinctions between saturated and *trans* fats, the agency has reconsidered the position that the two fatty acids should be declared as one combined entity. Declaration of the amount of *trans* fat on a separate line from saturated fat on the nutrition label is consistent with the possibility that the health benefits of *trans* fat labeling may be due to changes in LDL–C alone (Method 1), or to changes in both LDL–C and HDL–C (Method 2).

In response to the comment about relative risk in the prospective studies, FDA acknowledges that relative risk estimates in prospective studies will depend on the base risk used for comparisons and this dependence on base risk may result in inaccuracies when the relative risk is related to the absolute risk in other studies or in the general population. However, FDA does not agree that this difference would change the basic conclusion of the prospective

studies, that the CHD risk associated with *trans* fat in the prospective studies is much greater than the CHD risk expected due to either Method 1 (LDL–C) or Method 2 (LDL–C and HDL–C). In the 14-year followup of the Nurses Health Study (Ref. 38), the increased risk of CHD associated with *trans* fat intake compared with carbohydrate intake was more than ten times the increased risk for the same amount of saturated fat compared with carbohydrate. This comparison between *trans* fat and saturated fat was in contrast to the prediction based on Method 1 (LDL–C) or Method 2 (LDL–C and HDL–C). In Method 1, *trans* fat would be predicted to be associated with about the same increased risk as saturated fat, and in Method 2, *trans* fat would be predicted to be associated with about twice as much increased risk as saturated fat, comparing both with carbohydrate. This comparison was within a single study, so the difference between the results of this study and what would have been expected due to Method 1 or 2 cannot be attributed to any differences in baseline risk between studies. Moreover, although participants in large prospective studies have different baseline risks of CHD, the increased risk associated with known risk factors is often reasonably consistent across many of the studies. For example, the increased CHD risk associated with saturated fat for female nurses from 1980 to 1994 (Ref. 38) was quite similar to that for male employees of Western Electric Co. from 1958 to 1976 (Ref. 67) (64 FR 62746 at 62771). The changes in CHD risk associated with total cholesterol and HDL–C for male physicians from 1982 to 1987 was comparable to that for men and women from Framingham, MA in the 1970s (Ref. 131). Thus, FDA disagrees with the comment about relative risk in the prospective studies, and maintains that the prospective studies do suggest that there may be additional mechanisms, besides changes in LDL–C and HDL–C, by which

trans fat contributes to CHD risk. However, as discussed previously in this section, and in the November 1999 proposal (64 FR 62746 at 62771), FDA did not use the results of the prospective studies in its quantitative estimate of the health benefits of *trans* fat labeling. The sole use of the prospective studies was to suggest that there may be additional mechanisms by which *trans* fat contributes to CHD. The prospective studies thus indicate the direction of the uncertainty in the benefits estimate: That the actual benefits may be higher than the benefits estimated using Methods 1 and 2.

In response to the comments about the Ascherio et al. regression equation as discussed in the IOM/NAS report (Ref. 140), FDA notes that according to the NEJM, all submissions to the journal are peer-reviewed before publication. The comments did not cite any published articles questioning the 1999 Ascherio et al. paper (Ref. 83), and did not submit data from the unpublished work that the comments asserted could provide an alternate explanation for the Ascherio et al. results. As noted in section IV of this document, the paper by Ascherio et al. is not the only information that the IOM/NAS used in concluding that *trans* fatty acid consumption should be as low as possible in order to decrease CHD risk (see comment 3). Additionally, the Ascherio paper is not the only information in the IOM/NAS report that supports a positive linear trend for *trans* fat intake and LDL–C and risk of CHD. For example, as mentioned previously in this section (see comment 39), the study of Lichtenstein et al. (Ref. 82), using six test diets at different levels of *trans* fat intake, found a positive linear trend for *trans* fat intake and LDL–C level. In discussing *trans* fat intake and HDL–C, the IOM/NAS report references work by Zock, Mensink, and Katan (Refs. 69 and 154). These papers pertain not only to HDL–C but also to LDL–C. The work of Zock and colleagues (Refs. 62, 69,

and 154) gives one regression equation showing a positive linear trend between *trans* fat intake and LDL–C and another regression equation showing a negative linear trend between *trans* fat intake and HDL–C.

As noted in section IV and in this section of this document, FDA's primary rationale for *trans* fat labeling is the effect of *trans* fat intake on LDL–C. Additionally, the economic analysis uses changes in both HDL–C and LDL–C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule is the effect of *trans* fat on LDL–C. Therefore, as stated in the November 1999 proposal (64 FR 62746 at 62770), for purposes of economic analysis we used the equations of Zock et al. (Refs. 62 and 69) to estimate the effects of *trans* fat on LDL–C and HDL–C separately and did not use the equation of Ascherio et al. (Ref. 83), which estimates the positive linear trend between *trans* fat intake and the lipid ratio, LDL/HDL. FDA's Method 2, using the equations of Zock et al. (Refs. 62 and 69) for changes in both LDL–C and HDL–C, is different than the method of Ascherio et al. (Ref. 83), which uses changes in the lipid ratio, LDL/HDL. However, what FDA's Method 2 and Ascherio's method have in common is that they each provide a quantitative estimate of the adverse effects of *trans* fat on CHD risk using changes in both LDL–C and HDL–C.

As stated previously in this section (see comment 39), the regression equations of Zock et al. (Ref. 69), showing a positive linear trend between *trans* fat intake and LDL–C, are consistent with newer regression equations in a study published in 2001 by Muller et al. (Ref. 130). Thus, there is a body of research, including the work of Ascherio et al. (Ref. 83), Zock et al. (Refs. 62, 69 and 154), Lichtenstein et al. (Ref. 82) and Muller et al. (Ref. 130), that supports the existence of a linear trend for *trans* fat intake and LDL–C levels,

consistent with the conclusions of the IOM/NAS (Ref. 140). As discussed in the IOM/NAS report, the existence of a linear trend of saturated fat and LDL–C is very well-established, as shown by three sets of regression equations described in the IOM/NAS report (Ref. 140, Figure 8–3, pp. 8–47 to 8–48). Thus, the existence of a positive linear trend for *trans* fat intake and LDL–C, as shown by a body of research (Refs. 62, 69, 82, 83, 130, and 154) and recognized by the IOM/NAS (Ref. 140) is not unusual, considering that there is also a positive linear trend between saturated fat intake and LDL–C. Therefore, FDA is not convinced by the comments questioning the existence of linear trends between *trans* fat and lipid levels. FDA finds that, for the purposes of economic analysis, it is appropriate to quantitate the health benefits of *trans* fat labeling using regression equations (Refs. 62 and 69) describing a positive linear trend between *trans* fat intake and LDL–C and a negative linear trend between *trans* fat intake and HDL–C.

(Comment 42) One comment stated that FDA's estimate of benefits of the November 1999 proposal neglected to account for the overall reductions of mortality and morbidity from heart disease that have been occurring in the United States for the past few decades. According to the comment, FDA should have projected the future reduction in heart disease that would be expected in the absence of labeling. With such a projection, the baseline for heart disease morbidity and mortality would be progressively lower over time, and the numbers of heart attacks and deaths avoided due to *trans* fat labeling would be commensurately reduced compared with FDA's estimate. One comment stated that an overall decline in CHD from 1970 to 1990 coincided with a decline in intake of fat and saturated fat. The comment stated that margarine intake (per person) was constant during this period. Therefore, the comment

concluded that substituting margarine for high saturated fat and cholesterol products had proved beneficial in decreasing CHD.

FDA agrees that the rate of heart disease mortality and morbidity in the United States has been decreasing for several decades (Refs. 132 and 133). For example, the age-adjusted death rate from CHD declined from approximately 290 per 100,000 in 1979 to 190 per 100,000 in 1996 (Ref. 133). However, because the risk of CHD is greater at older ages and the U.S. population is aging, the decline in the overall (crude) CHD death rate in this period was more modest, from approximately 225 per 100,000 to 180 per 100,000. Moreover, because of the increase in the total population, the decline in annual CHD deaths in this period was even more modest, from approximately 550,000 to 500,000, about a 10 percent decrease over 17 years. The number of deaths was fairly level during the period, 1992 through 1996. Thus, the baseline number of CHD deaths, as opposed to age-specific rates, has historically declined at a modest rate, and has been fairly level in recent years. Therefore, FDA did not correct for this in its projection of heart attacks and deaths avoided due to *trans* fat labeling. In response to the comment about correcting its estimate for overall reductions in heart disease over time, FDA acknowledges that, if the actual number of CHD deaths declines in the future, omitting this correction would result in a modest overestimate of the health benefits of *trans* fat labeling.

Regarding the comment about correlations of changes in dietary intake with declines in CHD from 1970 to 1992, information on *trans* fat intake is limited, as noted in section IV of this document. Therefore, although margarine intake was approximately constant, it is not known whether overall *trans* fat intake increased, decreased or remained the same during this period.

Furthermore, the causes of the decrease in CHD over this time period have not been identified. Decreases in CHD risk factors, such as serum lipids, and decreases in saturated fat intake probably played a role, but the relative contributions of decreases in various risk factors and changes in medical care for heart attack patients are not adequately explained (Ref. 132). Therefore, FDA disagrees with the comment's conclusion that time trends in CHD incidence demonstrate a beneficial effect of margarine intake on incidence of CHD.

Based on the comments received and its own re-evaluation, FDA is not making any changes in the sample calculations for changes in CHD risk (table 8) and the factors for changes in serum lipids with substitution of different macronutrients (table 9), described earlier in this section. Earlier in this section, FDA has revised its estimate of projected decreases in *trans* fat intake due to labeling (table 2) and discussed the likely substitutions of different types of fat for *trans* fat. Using this information, FDA revised the expected changes in CHD risk due to *trans* fat labeling, shown in table 10.

TABLE 10.—PREDICTED CHANGES IN CHD RISK DUE TO *Trans* FAT LABELING ACCORDING TO MACRONUTRIENT SUBSTITUTION FOR *Trans* FAT

Time after Effective Date for Final Rule[1]	Decrease in *Trans* Fat Intake (% of Energy)	Source of Decrease	Substitution for *Trans* Fat	Percent Decrease in CHD Risk		
				Method 1, LDL	HDL	Method 2, LDL and HDL
3 years	0.0378	Consumer choice and margarine reformulation	mono	-0.056%	-0.053%	-0.108%
			mono + poly	-0.061%	-0.049%	-0.110%
			mono + sat	-0.027%	-0.062%	-0.090%
			Model	-0.052%	-0.054%	-0.106%

[1] The time after the effective date for the final rule includes 3 years for decreases in *trans* fat intake to result in changes in CHD risk.

Approximately 3 years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows that the 0.0378 percent of energy decrease in *trans* fat intake expected to occur by the effective date of the rule will result, 3 years after the effective date, in a 0.052

percent decrease in CHD risk using Method 1 and a 0.106 percent decrease in CHD risk using Method 2. FDA estimated these decreases in risk using a mathematical model that accounted for the three likely substitutions for *trans* fat in reformulation of margarine and direct consumer choice, discussed previously. Table 10 shows the predicted decrease in CHD risk for each of the substitutions separately, and the overall estimate from the mathematical model.

3. Value of Changes in Health

In the previous sections, FDA presented potential changes in food markets because of this final rule and described calculations of the decreases in CHD that would result from those market changes. Uncertainties in these analyses include:

- The size of consumer substitutions among existing products;
- The amount of producer reformulation to avoid losing market shares;
- The types of ingredient substitutions producers will make to reduce the amount of *trans* fat in their products; and,
- The decrease in CHD that will result from decreased *trans* fat in the diet.

FDA used three specific substitutions to represent the range of likely ingredient substitutions for *trans* fat in margarine: (1) 100 percent *cis*-monounsaturated fat, (2) a mixture of 50 percent *cis*-monounsaturated and 50 percent *cis*-polyunsaturated fat, or (3) a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat (Ref. 73).

FDA has identified these likely substitutions, but recognizes that once reformulation begins, different combinations of ingredients may emerge. In order to estimate the health effects of reformulation, however, it is less important to identify the exact formulas to be used than it is to identify the range of possible changes in CHD risk. To estimate the potential health benefits

from the reformulation of margarine FDA used a distribution of effects based on the distribution of possible changes in CHD risk associated with the three ingredient substitutions. FDA used a distribution rather than a weighted average because we did not know which combination was most likely, or what distribution of combinations would emerge.[3]

FDA estimated the benefits from the final rule for two methods. The two methods give low and high estimates of the change in CHD risk brought about by changing intakes of *trans* fat. Method 1 assumes that the reduction in CHD risk associated with reduced *trans* fat intakes comes about only through the reduction in LDL–C. Method 2 assumes that the reduction in CHD risk comes about through a combination of reducing LDL–C and increasing HDL–C. Method 2 results in higher benefit estimates than Method 1.

The reduction in CHD risk is highly uncertain primarily because of the difficulties in estimating the amount of reformulation, consumer response, and the reduction in CHD risk due to a decrease in *trans* intake. Also, these changes will occur over time and can be affected by other, unanticipated events. FDA dealt with the uncertainty by estimating a range of possible reductions in CHD risk associated with the final rule. The low and high estimated benefits can be interpreted as a range of potential effects. When we lacked direct evidence on uncertain values, we dealt with the uncertainty by choosing values that generated lower-bound estimates of benefits. This practice and the evidence in the previous section both imply that the actual realized benefits may exceed the range given by the two methods.

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[3] The formal distribution we used was a BetaPERT, which uses three points: a minimum, an intermediate, and a maximum. The model used the change in CHD risk for a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat as the minimum, the change with 100 percent *cis*-monounsaturated fat as intermediate, and the change for a mixture of 50 percent *cis*-monounsaturated and 50 percent *cis*-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.

a. *CHD morbidity and mortality prevented.* FDA calculated the benefits from the final rule as the reduction (from the baseline) in CHD multiplied by the value of preventing both fatal and nonfatal cases of CHD. FDA assumed that the cases of CHD prevented by this rule will have the same proportions of fatal and nonfatal cases as currently exist in the population. The AHA estimates that 1.1 million heart attack cases of CHD occur annually, with 40 percent of them fatal (Ref. 134). The average years of life lost per fatal case is 13, or 8 years discounted to the present at 7 percent. FDA used these estimates as the baseline for the estimated benefits. The number of cases varies from year to year, so FDA treated the annual number of cases as a distribution with a mean equal to 1.1 million (and a standard deviation of 110,000). FDA applied the estimated decline in the probability of CHD to the baseline to get estimates of the number of cases and fatalities prevented by the final rule. FDA used these estimates in the analysis for the proposed rule, and comments on this are discussed in the previous section on changes in health states. FDA estimated the effects using Method 1, which considers changes only in LDL–C, and using Method 2, which considers changes in both LDL–C and HDL–C.

The benefits are expected to begin 3 years after the effective date. The 3–year lag occurs because a dietary change takes several years to begin to affect the CHD risk (Ref. 137). With Method 1, FDA estimated that 3 years after the effective date, the final rule would annually prevent 600 cases of CHD and 240 deaths. Preventing 240 deaths would annually save about 1,920 discounted life years. With Method 2, FDA estimated that 3 years after the effective date, the final rule would annually prevent 1,200 cases of CHD and 480 deaths, saving about 3,840 discounted life years. Because the association between *trans*

fat consumption and CHD through changes in LDL–C is more conclusive, the benefits estimated using Method 1 should be regarded as more certain than the benefits estimated using Method 2.

b. *Value of CHD morbidity and mortality prevented.* In the proposed analysis, the per case valuations of morbidity and mortality prevented were estimated. There was no controversy over these estimates. The average cost per fatal case of CHD is about $836,000. The average cost per nonfatal case is about $281,000.

The annual benefits of the final rule equal the number of deaths prevented multiplied by the cost per death, plus the number of nonfatal cases prevented multiplied by the costs per nonfatal case. Because these benefits occur at different times and recur annually, they must be discounted to the time of publication of this final rule. Table 11 shows the timing of the undiscounted expenditures and the present value (discounted at 7 percent) of the costs at the time of publication of the final rule. Because benefits continue in perpetuity, the present value calculation has been made of an infinite stream of benefits discounted at 7 percent.

TABLE 11.—TIMING OF UNDISCOUNTED BENEFITS AND PRESENT VALUE OF BENEFITS (DISCOUNTED AT 7 PERCENT)

	Year 3 and Annually After the Effective Date	Present Value as of the Effective Date
Method 1	$234 million	$4.1 billion
Method 2	$476 million	$8.3 billion

F. Summary of Benefits and Costs

Table 12 shows the timing of the discounted benefits and costs estimated for this rule, as well as the totals. Although the rule will generate high setup costs, the later benefits should dwarf those costs. The effectiveness of this final rule can also be seen in the relatively low cost per life year saved. For example, if we express the one time costs as annualized cost over 20 years (discounted

at 7 percent), the medium cost estimate in table 12 comes to about $16 million per year. With Method 1, the cost per life year saved would be $10,000 ($16 million/4,000 life years). These ratios would be even lower if we included the quality-adjusted life years associated with nonfatal cases. The deaths prevented alone demonstrate the effectiveness of this final rule.

TABLE 12.—SUMMARY OF COSTS AND BENEFITS BY YEAR AFTER PUBLICATION, DISCOUNTED TO EFFECTIVE DATE, IN MILLIONS OF DOLLARS

		Effective Date							
	Years After Publication	2	3	4	5	6	7		Infinite Stream
Costs									
Low		$106	none	none	none	none	none	...	$106
Medium		$163	none	none	none	none	none	...	$163
High		$255	none	none	none	none	none	...	$255
Benefits									
Method 1	Annual	none	none	none	$234	$219	$205	...	
	Cumulative				$234	$453	$658	...	$4,100
Method 2	Annual	none	none	none	$476	$446	$416	...	
	Cumulative				$476	$922	$1,338	...	$8,345

G. Peer Review

FDA submitted this economic analysis to the Interagency Economic Peer Review (IEPR) for peer review. The IEPR is a voluntary review process composed of, but not limited to, Federal economists and analysts who review Regulatory Impact Analyses and Regulatory Flexibility Analyses prior to OMB clearance to improve the quality of economic analysis.

Two Federal economists reviewed this analysis. Their specific comments and FDA's responses are detailed in Ref. 155. FDA made the following changes to the analysis in response to the comments of the reviewers:

- Added several sections to repeat information contained in the analysis that accompanied the proposal to provide more background and context for the reader,
- Made some style changes for clarity,
- Added explanations for how some numbers were calculated,

• Added references for the European market experience with margarine reformulation,

• Addressed the comments on costs more explicitly,

• Explained why the costs of reformulation are included in the analysis,

• Added an introduction describing the plan of the benefits model and the linkages between the various parts of the model,

• Corrected our description of study subjects in the 1994–1996 Diet and Health Knowledge Survey (DHKS) in discussing Ref. 119.

X. Final Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this final rule would have a significant economic impact on a substantial number of small entities.

B. Economic Effects on Small Entities

1. Number and Type of Small Entities Affected

FDA used data from the 1999 County Business Patterns (Ref. 136) to estimate the number of small businesses affected by this rule. Table 13 shows the number of small businesses affected by the North American Industry Classification System (NAICS). The final rule will affect almost all manufacturers of packaged, labeled food sold in the United States, with the exception of exempt manufacturers. The criteria for exemption are: (1) Annual

sales of fewer than 100,000 units; (2) no claims or other nutrition information on product labels, labeling, or advertising; (3) fewer than 100 full-time employees; and (4) filing of a notice with the Office of Food Labeling (§ 101.9(j)(18) 2002). FDA has previously estimated that the exemption for all foods would affect about 1.8 percent of FDA regulated foods by volume (see 58 FR 2927 at 2928, January 6, 1993). FDA estimated the effects of exemptions only for the total costs to small businesses.

TABLE 13.—NUMBER OF SMALL ESTABLISHMENTS BY NAICS CODE

Category Description	NAICS Code	No. of Establishments
Rice	311212	60
Refined or Blended Fats and Oils	311225	140
Breakfast Cereals and Related Products	311230	60
Chocolate and Confectionery Products Made from Cacao Beans	311320	150
Nonchocolate Confectionery Products	311340	590
Frozen Fruits and Vegetables	311411	230
Frozen Specialties, NEC	311412	380
Specialty Canned Food	311422	140
Dried and Dehydrated Foods	311423	180
Fluid Milk	311511	570
Creamery Butter	311512	30
Cheese	311513	520
Dry, Condensed and Evaporated Milk	311514	210
Ice Cream and Frozen Desserts	311520	420
Fresh and Frozen Seafood	311712	660
Commercial Bakery Products	311812	2760
Frozen Bakery Products	311813	230
Cookies and Crackers	311821	390
Flour Mixes and Dough Made from Purchased Powder	311822	230
Other Snack Foods	311919	400
Mayonnaise, Dressings and Other Prepared Sauces	311941	340
Spices and Extracts	311942	280
Perishable Prepared Food	311991	480
All Other Miscellaneous Food Preparations	311999	850
Pharmaceutical Preparations (NAICS classification for dietary supplements	325412	880
Total		11,180

2. Costs to Small Entities

FDA calculated the costs to small businesses with the same basic model that we used in section IX.D of this document to estimate the total costs. Although the basic model is the same for large and small firms, the individual components of costs differ for large and small firms. On average, small firms produce fewer products, and market fewer labels. FDA assumes that the estimated margarine reformulation will be done by large producers.

FDA estimated the total costs of the final rule to small business by estimating the individual categories of costs and summing them. The first category is testing costs. Small businesses would need to test their products to determine the amounts of *trans* fats. FDA did not have direct estimates of the number of products produced by the small businesses affected by the final rule. FDA estimated the number of products produced by small businesses by using a sample from the Enhanced Establishment Database (EED) and assuming that the proportion of all products produced by small businesses was the same as the sample proportion (85 percent). FDA then multiplied the 60,000 products estimated to be tested (table 3 of this document) by the proportion of products produced by small businesses (85 percent) to estimate that 51,000 products will be tested by small businesses. Table 14 shows the range of testing costs for all small businesses.

TABLE 14.—RANGE OF PER PRODUCT AND TOTAL TESTING COSTS FOR SMALL BUSINESSES

	Low	Medium	High
Cost per Product	$261	$291	$371
Total Testing Cost	$13,311,000	$14,841,000	$18,921,000

Under this final rule many more labels will have to be changed than under the proposed rule. FDA has used the new Labeling Cost Model to re-estimate the relabeling costs of this final rule. FDA estimated reprinting costs for information panels on a per label (SKU) basis. FDA assumed that the